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(54) PROTHESE ENDOVASCULAIRE AVEC MECANISME DE RETENUE DES SUTURES
(54) ENDOVASCULAR PROTHESIS WITH SUTURE HOLDER

(57)

There is disclosed an endovascular prosthesis with suture holder which can be introduced endoluminally into a vascular channel for application, which comprises a prosthetic body with cylindrical walls and open bases that can be radially expanded up to the limit at which its external surfaces contact the damaged vascular walls of the vascular channel, with the internal surfaces of the body forming a prosthetic circulatory passage. A number of connectors are provided and distributed such that they encircle the cylindrical walls of the prosthetic body and are attached to the internal surfaces of the cylindrical walls. In each connector, the rotary end is disconnectable from a respective semi-flexible cable as an applicator of sutures, which cable extends beyond the prosthetic passage, terminating in an external rotary control end. Passing through each connector and the adjacent cylindrical wall of the prosthetic body is a spiral suture, the anchoring end of which is inserted in the rotary end of its respective semi-flexible cable.



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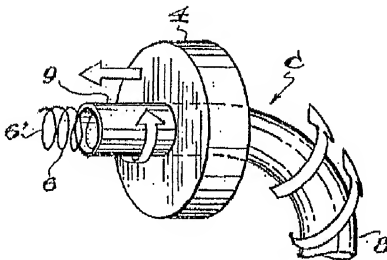
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(54) **PROTHESE ENDOVASCULAIRE AVEC MECANISME DE
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ABSTRACT

There is disclosed an endovascular prosthesis with suture holder which can be introduced endoluminally into a vascular channel for application, which comprises a prosthetic body with cylindrical walls and open bases that can be radially expanded up to the limit at which its external surfaces contact the damaged vascular walls of the vascular channel, with the internal surfaces of the body forming a prosthetic circulatory passage. A number of connectors are provided and distributed such that they encircle the cylindrical walls of the prosthetic body and are attached to the internal surfaces of the cylindrical walls. In each connector, the rotary end is disconnectable from a respective semi-flexible cable as an applicator of sutures, which cable extends beyond the prosthetic passage, terminating in an external rotary control end. Passing through each connector and the adjacent cylindrical wall of the prosthetic body is a spiral suture, the anchoring end of which is inserted in the rotary end of its respective semi-flexible cable.

I - GROUNDS

This invention consists of an **endovascular device with suture holder** that permits creation of a firm union between the prosthesis and the vascular walls with no need to introduce suture applicator devices into the vascular channel.

To treated diseases of the arterial and venous channels, recourse is had to endovascular treatments based on the application of expandable prostheses or endoluminal expanders that permit the affected vascular walls to be covered and thus provide an effective solution to problems that would otherwise cause a high rate of mortality.

Nonetheless, the new application techniques and devices must solve problems such as how to avoid vascular dilation subsequent to the treatment causing periprosthetic losses resulting in consequences difficult to solve.

To avoid this type of problem, internal sutures are used that prove highly effective in obtaining a firm union between the vascular walls and the body of the prosthesis.

These endovascular sutures consist of metal spirals provided with an sharp penetrating end and an anchoring end that are applied by means of devices equipped with rotary applicator heads. In this manner, the above-mentioned spirals pass through the walls of the prosthesis first, and then the vascular walls, achieving a very firm union by means of which the sutured prosthesis conveniently accompanies the dilation of the vascular channel.

However, the known devices used for this type of treatment include a set of means such as distal or proximal inflatable balloons, tubular parts that provide a surgical method in which a rotary pusher for the above-cited spiral sutures, auxiliary lines, etc., can function.

In addition, these devices have a function based on the fact that the operations for introducing the sutures are performed inside the vascular channel.

This device permits disposing of devices such as those mentioned, since both the sutures and the means of application are mounted on the prosthesis itself.

Basically it comprises a prosthetic body over the internal surfaces of which a number of connectors are distributed and attached; on the one hand, they connect the respective semi-flexible cables to external, rotary control ends while, on the other hand, they are passed through by respective spiral sutures controlled by said semi-flexible cables.

That is, the spiral sutures are already applied to the prosthetic body, as are the semi-flexible applicator cables. Once the prosthetic body is expanded, its external surfaces are backed against the vascular walls. With this arrangement, the rotary actuation of the semi-flexible cables permit the penetrating ends of the spirals to pass through the vascular walls.

This penetration continues until the anchoring tips of the above-cited spirals meets the bases of their respective connectors. In this manner, a firm union is created between the vascular channel and the prosthetic body and the semi-flexible cables are simply disconnected and withdrawn.

This creates an endovascular prosthesis that does not require the introduction of additional applicators, that simplifies placement operations and is more economical than other devices currently in use.

II - Illustration

For greater clarity and better comprehension of the subject of the invention, it is illustrated with various figures showing one of the preferred methods of embodiment, all as a simple illustrative and not limitative example.

Figure 1 is a perspective view of the interior passage of the prosthetic body showing the semi-flexible cables and corresponding connectors.

Figure 2a is a perspective view of a connector with its respective semi-flexible cable. A spiral suture appears through the mouth of the connector.

Figure 2b is a perspective view, as in Figure 2a, but showing how the rotation of the cable causes the spiral to advance.

Figure 3 is a perspective view of the internal surface of the prosthetic body.

Figure 4 is a perspective view of the external surface of the prosthetic body.

Figure 4a is a longitudinal cross-section of the prosthetic body and the vascular channel for the application once the spiral sutures have been applied and the respective semi-flexible cables disconnected.

Figure 5a is a perspective detail of a connector and the applicator end of the semi-flexible cable in which the application movements of the spiral suture are shown.

Figure 5b is a detail, as in Figure 5a, but showing the disconnection movements of the applicator end of the semi-flexible cable.

In the various Figures, the same reference numbers indicate the same or similar parts, and the sets of various components are indicated by letters.

List of the Main References:

- (a) vascular channel for application
- (b) prosthetic body
- (c) semi-flexible cables
- (1) cylindrical walls of prosthetic body (b)
- (1') prosthetic passage delimited by cylindrical walls (1)
- (2) internal surfaces of cylindrical walls (1)
- (3) external surfaces of cylindrical walls (1)
- (4) connector in form of small disk
- (4') base of connector (4)
- (4'') mouth of connector (4)
- (5) vascular walls of vascular channel (a)
- (6) spiral sutures
- (6') sharpened penetrating end of spiral suture (6)

- (7) anchoring end of spiral suture (6)
- (8) long body of semi-flexible cable (b)
- (9) rotary applicator end, disconnectable from cable (b)
- (9') external rotary control end of cable (b).

III - Main Objective

For the purposes specific, this endovascular prosthesis with suture holder is of the type that, since it can be introduced endoluminally into vascular channel (a) for the application, comprises prosthetic body (b) with cylindrical walls (1) and open bases, the is expandable radially up to the limit at which its external surfaces (3) come into contact with damaged vascular walls (5) of the above-cited vascular channel (a), with internal surfaces (2) of said body (b) forming prosthetic circulatory passage (1'); said endovascular prosthesis is characterized in that it comprises:

a) a number of connectors (4) that, distributed such that they encircle the cylindrical walls (1) of prosthetic body (b), are attached to internal surfaces (2) of said cylindrical walls (1);

b) in each connector (4), rotary end (9), which is disconnectable from respective semi-flexible cable (c) for applying sutures (6), which cable (c) extends beyond said prosthetic passage (1'), ending in an external rotary control end (9'); and

c) passing through each connector (4) and cylindrical wall (1) adjacent to said prosthetic body (b), respective spiral suture (6), the anchoring ends (7) of which are inserted in said rotary end (9) of its respective semi-flexible cable (b).

IV - Description

This invention consists of an **endovascular prosthesis with suture holder** that, in general terms, comprises prosthetic body (b) on internal surfaces (2) of which a number of connectors (4) are distributed and attached that, on the one hand, connect respective semi-flexible cables (b) ending in external rotary control ends (9'), while, on the other hand, they are passed through by respective spiral sutures (6) controlled by said semi-flexible cables (b).

More particularly, the endovascular prosthesis consists of prosthetic body (b) with cylindrical walls (1) and open bases that can be introduced into vascular channel (a) for the application until it reaches its position with regard to the damaged vascular walls (5). It is a prosthetic body (5) that can be expanded radially up to the limit at which its cylindrical walls (1) contact above-cited vascular walls (5).

In various methods of embodiment, prosthetic body (b) can be composed of a thermo-expandable material or a material expandable by means on an inflatable balloon or similar device.

Cylindrical walls (1) of prosthetic body (b) are delimited by external (3) and internal (2) surfaces. It is precisely on the internal walls (2) that a number of connectors (4) are attached that, in the method of embodiment described, consist of parts in the shape of small disks, the mouth (4'') of which is placed against internal surface (2), while its base (4') remains exposed inside prosthetic passage (1') made up of cylindrical walls (1). These connectors (4) are distributed inside cylindrical walls (1), lining them in a circular manner.

At each connector (4), there terminates respective semi-flexible cable (c) for application of sutures (6), for which reason, for each connector (4) available, the prosthesis has a semi-flexible cable (c). This latter (c) consists of long body (8) with applicator end (9) that can be disconnected from connector (4) to which it is connected. Starting from this disconnectable applicator end (9), semi-flexible cable (c) extends beyond the prosthetic passage (1') until it projects from vascular channel (a), ending in an external control end (9') which can be connected to a rotary device.

Moreover, each connector (4) is passed through by respective spiral suture (6) provided with sharpened penetrating end (6') and, at the opposite end, with anchoring end (7). These spiral sutures (6) pass through connectors (4) and prosthetic walls (1) equipped at two alternative end positions: one for prosthetic positioning, at which anchoring ends (7) are inserted into applicator ends (9) of their respective semi-flexible cables (c); and the other position for placement of the prosthesis, in which sharpened ends (6') of said spirals (6) protrude through prosthetic walls (1) and pass through vascular walls (5) for the application.

In this second, prosthetic-placement position, bases (4') of connectors (4) constitute a penetration stop for anchoring ends (7) of spiral sutures (6).

The unit functions in the following manner:

By means of any suitable introductory device, the endovascular prosthesis is introduced through vascular channel (a) for the application until it reaches its position with regard to damaged vascular walls (5).

Under these conditions, prosthetic body (b) is contracted and spiral sutures (6) passed through connectors (4) and cylindrical walls (1) of prosthetic body (b), although without projecting externally therefrom further than its external surface (3).

Once prosthetic body (b) is expanded, its external surfaces (3) are in contact with vascular walls (1). With this arrangement, the rotary actuation of semi-flexible cables (c) permits penetration ends (6') of spirals (6) to pass through vascular walls (5). This penetration continues until anchoring ends (7) of above-cited spirals (6) stop against bases (4') of respective connectors (4). In this manner, a firm union is created between vascular channel (a) and prosthetic body (b).

It is indubitable that, once this device is used in practice, changes can be made in certain design and form details without escaping from the fundamental principles substantiated clearly in the following Claims.

V - Claims

THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1) ENDOVASCULAR PROSTHESIS WITH SUTURE HOLDER: of the type that, since it can be introduced endoluminally into a vascular channel for application, comprises a prosthetic body with cylindrical walls and open bases that can be radially expanded up to the limit at which its external surfaces contact the damaged vascular walls of the above-cited vascular channel, with the internal surfaces of said body forming a prosthetic circulatory passage; characterized in that it comprises:

a) a number of connectors that, distributed such that they encircle the cylindrical walls of the prosthetic body, are attached to the internal surfaces of said cylindrical walls;

b) in each connector, the rotary end disconnectable from a respective semi-flexible cable as an applicator of sutures, which cable extends beyond said prosthetic passage, terminating in an external rotary control end; and

c) passing through each connector and the adjacent cylindrical wall of said prosthetic body, a respective spiral suture, the anchoring end of which is inserted in said rotary end of its respective semi-flexible cable.

2) ENDOVASCULAR PROSTHESIS WITH SUTURE HOLDER, pursuant to Claim 1: characterized in that the connectors consist of parts in the shape of small disks, the base of which constitutes a penetration stop for the anchoring end of the respective spiral suture.

3) ENDOVASCULAR PROSTHESIS WITH SUTURE HOLDER, pursuant to Claim 1: characterized in that the external control ends of the semi-flexible cables form connecting ends with a rotary device.

4) ENDOVASCULAR PROSTHESIS WITH SUTURE HOLDER, pursuant to Claim 1: characterized in that the spiral sutures pass through the connectors and the walls of the prosthetic body between two alternative end positions: one for prosthetic positioning, in which its anchoring ends are inserted in the ends of its respective semi-flexible cables; and another prosthetic-placement position in which the sharp ends of said spirals protrude through the prosthetic walls and pass through vascular walls for the application.

5) ENDOVASCULAR PROSTHESIS WITH SUTURE HOLDER, pursuant to Claim 1: characterized in that the walls of the prosthetic body are composed of a thermo-expandable material.

6) ENDOVASCULAR PROSTHESIS WITH SUTURE HOLDER, pursuant to Claim 1: characterized in that the connectors encircle the interior of the cylindrical walls, lining them in circular fashion.

FIG. 1

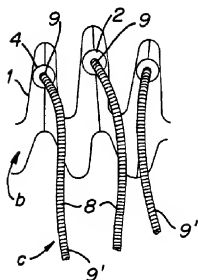


FIG. 2A

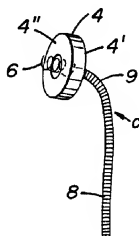


FIG. 2B

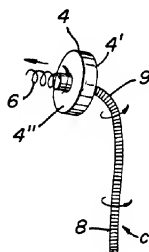


FIG. 3

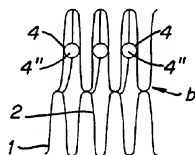
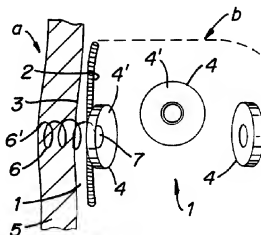
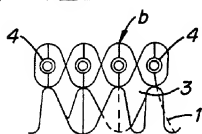


FIG. 4A

FIG. 4



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FIG. 5A

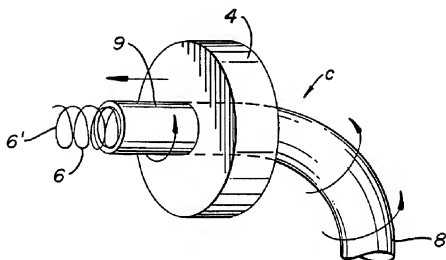
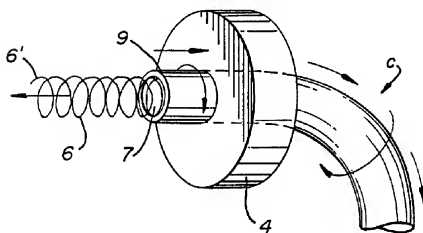


FIG. 5B



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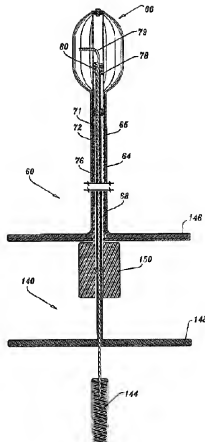
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(54) ENDOVASCULAR FASTENER APPLICATOR

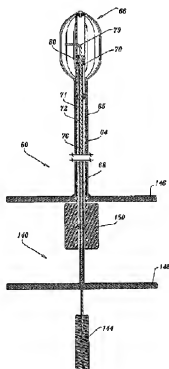
(57)

An endo-vascular fastener applicator (50) is provided for endo-luminal fastening a prosthetic (100) to a vessel with a fastener (80). The applicator (50) includes a tubular body (64) that is configured for positioning within a vessel, an expandable portion (66) disposed adjacent distal end of the tubular body, and deployed to support a prosthetic (100) in contact with an inner surface of a vessel. A drive assembly (60) is included for advancing a fastener (80) into the prosthetic (100). The endo-vascular fastener applicator (50) may include a control assembly (140). A delivery tube (72) may be included that is disposed for movement within the tubular body, and which defines a channel for movement of the drive assembly there within. The delivery tube (72) may include an applicator head (73). The applicator head (73) may include an injection mount (80) that is disposed for movement relative to a prosthetic (100). An endo-vascular fastener applicator system (50) is disclosed for repairing a damaged portion of a vessel. A method for endo-luminal repairing a damaged portion of a vessel is disclosed.





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(54) ENDOVASCULAR FASTENER APPLICATOR



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PCT

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(21) International Application Number: PCT/US99/21414 (22) International Filing Date: 17 September 1999 (17.09.99) (30) Priority Data: 60/101,050 18 September 1998 (18.09.98) US (71) Applicant (for all designated States except US): UNITED STATES SURGICAL CORPORATION [US/US]; 150 Glover Avenue, Norwalk, CT 06856 (US). (72) Inventors; and (75) Inventors/Applicants (for US only): PARODI, Juan Carlos [AR/AR]; Blanco Encalada 1543/47, (1428) Capital Federal (AR). RATCLIFF, Keith [US/US]; 14 Concorde Ridge, Newtown, CT 06470 (US). RENDE, Frank, M. [US/US]; 58 George Street, Stamford, CT 06902 (US). SHERTS, Charles, R. [US/US]; 443 Riverside Avenue, Westport, CT 06880 (US). (74) Agents: BARRESE, Rocco, S. et al.; Dilworth & Barrese, 333 Earle Ovington Boulevard, Uniondale, NY 11553 (US).		(81) Designated States: CA, JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>
(54) Title: ENDOVASCULAR FASTENER APPLICATOR		
(57) Abstract <p>An endo-vascular fastener applicator (50) is provided for endo-luminal fastening a prosthetic (100) to a vessel with a fastener (80). The applicator (50) includes a tubular body (54) that is configured for positioning within a vessel, an expandable portion (56) disposed adjacent distal end of the tubular body, and deployed to support a prosthetic (100) in contact with an inner surface of a vessel. A drive assembly (60) is included for advancing a fastener (80) into the prosthetic (100). The endo-vascular fastener applicator (50) may include a control assembly (140). A delivery tube (72) may be included that is disposed for movement within the tubular body, and which defines a channel for movement of the drive assembly (140). The delivery tube (72) may include an applicator head (73). The applicator head (73) may include an injection mount (80) that is disposed for movement relative to a prosthetic (100). An endo-vascular fastener applicator system (50) is disclosed for repairing a damaged portion of a vessel. A method for endo-luminal repairing a damaged portion of a vessel is disclosed.</p>		

ENDOVASCULAR FASTENER APPLICATOR

CROSS-REFERENCE TO RELATED APPLICATIONS

This Patent Application claims the benefit of U.S. Provisional Application Serial No. 60/101,050 filed September 18, 1998, by Parodi et al., the entire contents of which are hereby incorporated by reference.

BACKGROUND

1. Technical Field

This disclosure relates generally to vascular grafts for intraluminal delivery, and in particular, to a method and apparatus for repairing diseased or damaged sections of a vessel by fastening a prosthesis within the vessel.

2. Description of Related Art

Diseased or damaged blood vessels often cause weakening of the vessel wall resulting in an aneurysm whereby a blood vessel and especially an artery have a section of abnormal blood-filled dilation. For example, an abdominal aortic aneurysm is a sac caused by an abnormal dilation of the wall of the aorta, a major artery of the body as it passes through the abdomen.

The abdominal aortic aneurysm usually arises in the infrarenal portion of the arteriosclerotically diseased aorta, for example, below the kidneys. Left untreated, the aneurysm will eventually cause rupture of the sac with ensuing fatal hemorrhaging in a very short time. High mortality associated with rupturing led the state of the art into trans-abdominal surgical repair of abdominal aortic aneurysms.

Surgery involving the abdominal wall, however, is a major undertaking with

associated high risks. This type of surgery, in essence, involves replacing the diseased and aneurysmal segment of blood vessel with a prosthetic device which typically is a synthetic tube, or graft, usually fabricated of either DACRON™, TEFLON™, or other suitable material.

5 The present state of the art for intraluminal repair of a vessel does not fasten a prosthesis to the remaining aortic wall. For example, U.S. Patent Nos. 5,571,171 and 5,571,173 disclose a method and apparatus for treating an abdominal aortic aneurysm by supplying a prosthesis or an aortic graft for intraluminal delivery that does not fasten the graft to the remaining aortic wall.

10 Presenting an aortic graft through the aorta by intraluminal delivery avoids major invasive surgery. The '171 and '173 patents disclose an aortic graft that is delivered intraluminally to the aneurysm site. The aortic graft is secured to the remaining aortic wall by a balloon that is inflated thereby causing the graft to contact and adhere to the remaining aortic wall.

15 The major disadvantages related to the combination of endovascular expanders, such as a balloon or stent, and prosthesis is the dilation of the natural artery with consequent migrations and periprosthetic losses. Upon withdrawal of the expander, the tissue is caused to collapse and the prosthesis disengages from the remaining aortic wall and tends to migrate to a location away from the aneurysm site to be repaired. The migration and movement of the disengaged aortic graft would then obstruct the affected vessel. The migration and movement of the aortic graft requires further treatment on the patient to remove the failed attempt to attach the aortic graft to the remaining aortic wall.

20 Further treatment may include major surgery that is hazardous and traumatic to the patient. Major surgery to remove the aortic graft defeats the benefits of intraluminal delivery of the aortic graft. The current state of the art does not disclose a fastener applicator that intraluminally delivers a vascular graft and endoluminally applies internal fasteners to fasten a prosthesis in place.

25 Accordingly, there is a present need for a fastener applicator that intraluminally

delivers a vascular graft to a site within a vessel and applies fasteners to pass through both a prosthesis and the thickness of a vessel wall. The fastened prosthesis should also have the capability of following dilation of a vessel.

5

SUMMARY

An endovascular fastener applicator for endoluminally delivering prostheses for treating a vessel is disclosed. The endovascular fastener applicator includes a delivery assembly and a control assembly. The delivery assembly delivers a graft to a site within
10 a vessel and fastens the prosthesis to a vessel by passing a fastener therethrough. The delivery assembly may include an outer sleeve, delivery tube and drive assembly for fastening a prosthesis to a vessel. The control assembly controls operation of the graft delivery catheter. At least a portion of the applicator can be fabricated from a shape memory material. The applicator can be configured to deploy multiple fasteners.

15 In one embodiment, an endovascular fastener applicator is provided for endoluminally fastening a prosthetic to a vessel with a fastener, in accordance with the present disclosure. The applicator includes a tubular body that is configured for positioning within a vessel. An expandable portion is disposed adjacent a distal end of the tubular body and is deployable to support a prosthetic in contact with an inner surface
20 of a vessel. A drive assembly is also included for advancing a fastener into the prosthetic. The drive assembly can be coaxially disposed within the tubular body. The drive assembly may include a curved portion oriented at an angle of substantially 90° from a longitudinal axis defined by the tubular body. In an alternate embodiment, the drive assembly includes a drive rod having a rectangular cross-section. The drive rod
25 cooperates with an inner diameter of a fastener whereby movement of the drive rod causes advancement of a fastener. The drive assembly may be configured for axial and rotational motion.

The endovascular fastener applicator may include a control assembly that is

operatively connected to the drive assembly for extracorporeal control of the applicator. In one embodiment, the control assembly includes a handle having a pistol-grip trigger configuration.

5 The endovascular fastener applicator may include a delivery tube that is disposed for movement within the tubular body and which defines a channel for movement of the drive assembly therewithin. The delivery tube is configured for advancing a fastener within the tubular body. The delivery tube can be coaxially disposed with the tubular body. In another embodiment, the delivery tube includes an applicator head configured to facilitate deployment of the fastener. The applicator head may have a substantially
10 perpendicular orientation to a longitudinal axis defined by the delivery tube.

The fastener applicator may also include an elongate control positioned for movement within the tubular body. The expandable portion is operatively connected to a distal end of the tubular body and a distal end of the elongate control. The tubular body and the elongate control are manipulable to facilitate support of the prosthetic in contact
15 with an inner surface of a vessel. The elongate control can be coaxially disposed with the tubular body.

The expandable portion may include support members that define open interstitial regions therebetween. The support members can comprise a plurality of flexible wires. The support members may alternatively comprise a plurality of flexible tapes.

20 In one embodiment, the drive assembly may include at least one fastener guide configured to guide advancement of a fastener. Each fastener guide cooperates with a prosthetic for guiding advancement.

In another alternate embodiment, the applicator head includes an ejection mount that is disposed for movement relative to a prosthetic and configured for deployment of a plurality of helical fasteners. The ejection mount has an ejection head with a saw toothed face which is configured for engaging a prosthetic. A ratchet assembly may be included
25 that is configured to facilitate movement of the ejection mount.

In yet another alternate embodiment, an endovascular fastener applicator system

is disclosed for repairing a damaged portion of a vessel. The system includes at least one helical fastener and a prosthetic. Each helical fastener having a penetrating end and a limiting end. An endovascular fastener applicator, as discussed above, is also included. An applicator head, as discussed above, may be included, that is configured for engaging an interior portion of the prosthetic to facilitate uniform deployment of each helical fastener. A drive rod may have a cross-section corresponding to an interior cross-section defined by each helical fastener, and in cooperation, facilitate advancement and deployment of each helical fastener.

In an alternate embodiment, the prosthetic includes an interior band having anchor pads circumferentially spaced about and implanted within the band. The pads correspond to the open interstitial regions of the expandable portion. The drive assembly includes guide wires configured for guiding advancement of each helical fastener and have anchor legs adjacent a distal end of each of the guide wires. The anchor legs releasably engage the anchor pads prior to deployment of each helical fastener and are retractable from the prosthetic upon deployment of each helical fastener.

The applicator head may include an ejection mount configured for deploying at least one helical fastener and movable relative to an interior circumference of the prosthetic for deploying each helical fastener. The ejection mount includes an ejection head having a saw-toothed face for engaging the internal circumference of the prosthetic. The ejection head facilitates uniform deployment of each helical fastener.

A method for endoluminally repairing a damaged portion of a vessel is disclosed.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments are described herein with reference to the drawings, wherein:

FIG. 1 is a perspective view of one embodiment of an endovascular fastener applicator in accordance with the present disclosure;

FIG. 2 is a cross-sectional view, in part elevation, of an aortic graft placed at the site of an abdominal aortic aneurysm within the aorta;

FIG. 3 is an enlarged detail view of a portion of FIG. 2 illustrating the aortic graft secured to the remaining aortic wall and maintained in position by helical fasteners;

FIG. 4 is a cross-sectional view, in part elevation, of an aortic graft for treating an aortic aneurysm affecting the aorta and both iliac arteries;

FIG. 5 is a perspective view of a helical fastener;

FIG. 6 is a side elevation view of a helical fastener;

FIG. 7 is a bottom perspective view taken along line 7-7 of FIG. 6 of a helical fastener having a rectangular configuration at its limiting end for cooperating with a rectangular drive assembly;

FIG. 8 is a cross-sectional view taken along line 8-8 of FIG. 7 of a helical fastener;

FIG. 9 is a cross-sectional view, in part elevation, of an endovascular fastener applicator;

FIG. 10 is a cross-sectional view, in part elevation, of a distal portion of the applicator at the aneurysm site;

FIG. 11 is a cross-sectional view of the control assembly;

FIG. 12 is a cross-sectional view, in part elevation, of the applicator at the aneurysm site showing an expandable portion causing a prosthesis to contact a vessel wall;

FIG. 13 is a cross-sectional view of the control assembly;

FIG. 14 is a cross-sectional view, in part elevation, of the applicator at the aneurysm site showing advance of a delivery tube;

FIG. 15 is a cross-sectional view of the control assembly;

FIG. 16 is a cross-sectional view, in part elevation, of the applicator at the aneurysm site showing advance of a drive assembly;

FIG. 17 is a top view of a helical fastener defining a rectangular configuration at its limiting end for cooperating with a rectangular drive assembly, as shown in cross-section;

FIG. 18 is a cross-sectional view of the control assembly;

5 FIG. 19 is a cross-sectional view, in part elevation, of the delivery assembly showing rotation for insertion of a helical fastener;

FIG. 20 is a cross-sectional view, in part elevation, of an alternate embodiment of the applicator showing the delivery assembly at the aneurysm with fastener guides;

10 FIG. 21 is an enlarged detail view of a portion of FIG. 20 illustrating a helical fastener guided over a drive attached to a fastener guide;

FIG. 22 is a cross-sectional view, in part elevation, of a helical fastener taken along line 22-22 of FIG. 21;

15 FIG. 23 is a plan view, in part cross-section, taken along line 23-23 of FIG. 20 showing the applicator with fastener guides;

FIG. 24 is a perspective view of one embodiment of a fastener guide in accordance with the present disclosure;

FIG. 25 is a perspective view, in part cross-section, showing movement of the helical fastener over a drive prior to collapsing the fastener guide;

20 FIG. 26 is a perspective view, in part cross-section, showing the drive after the fastener guide is collapsed and the helical fastener deployed;

FIG. 27 is a perspective view, showing retraction of the drive and fastener guide;

25 FIG. 28 is a perspective view of an alternate embodiment of the control assembly;

FIG. 29 is a perspective view of the distal end of an alternate embodiment of the drive assembly loaded with a plurality of helical fasteners;

FIG. 30 is a perspective view showing a helical fastener for loading with a

channel of the drive assembly;

FIG. 31 is a perspective view of an alternate embodiment of a helical fastener;

FIG. 32 is a perspective view of an applicator head and helical fasteners prior to deployment into a prosthesis;

FIG. 33 is a perspective view of the helical fastener deployed into the prosthesis and artery;

FIG. 34 is a perspective view of an alternate embodiment of the applicator showing the expandable portion in an expanded state;

FIG. 35 is a perspective view of the expandable portion shown in FIG. 34 in a relaxed state;

FIG. 36 is an exploded view of the delivery assembly shown in FIG. 34;

FIG. 37 is an exploded view of the drive assembly shown in FIG. 34;

FIG. 38 is a perspective view of the drive assembly shown in FIG. 34;

FIG. 39 is a perspective view of an embodiment of an ejection mount ;

FIG. 40 is a perspective view of the ejection mount showing a set screw and cam divider for cooperating with the drive assembly;

FIG. 41 is a cross-sectional view of the applicator with the expandable portion in a relaxed state and a prosthetic having a sealing gasket;

FIG. 42 is a cross-sectional view, in part elevation, of the distal end of the applicator;

FIG. 43 is a cross-sectional view, in part elevation, with the expandable portion in an expanded state;

FIG. 44 is an enlarged cross-sectional view, in part elevation, of the distal end of the applicator;

FIG. 45 is a perspective view of the expandable portion in an expanded state and the ejection mount loaded with helical fasteners;

FIG. 46 is a cross-sectional view, in part elevation, with the ejection

mount pivoted for deployment of helical fasteners;

FIG. 46A is a perspective view, in part cross-section, an alternate embodiment of the ejection mount pivoted for deployment of helical fasteners;

5 FIG. 47 is a cross-sectional view, in part elevation, of the ejection mount engaging the aortic graft prior to deployment of helical fasteners;

FIG. 48 is a perspective view, in part cross-section, showing deployment of helical fasteners;

FIG. 49 is a perspective view, in part cross-section, showing retraction of the ejection mount;

10 FIG. 50 is a cross-sectional view, in part elevation, showing the ejection mount subsequent to deployment of a helical fastener; and

FIG. 51 is a top view of the applicator, showing movement of the ejection mount prior to deployment of a helical fastener.

15 **DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS**

As illustrated in FIG. 1, the present disclosure relates to an endovascular fastener applicator, generally referred to as numeral 50. Endovascular fastener applicator 50 delivers aortic graft 100, as shown in FIGS. 2 and 3, for repairing an abdominal aortic aneurysm 120 in aorta 124 having two iliac arteries 126L and 126R associated therewith, as well as a plurality of renal arteries 130 located above aneurysm 120 in fluid communication with aorta 124. Repairing the aneurysm includes fastening an aortic graft 100 to an aortic wall 132 by fasteners 80. Aortic graft 100, as well as other prostheses, may be utilized in the thoracic aorta, and can be used to repair thoracic aneurysms or thoracic dissecting aneurysms. Further, the fastener applicator 50 may also treat vascular trauma and other obstructive diseases with various prostheses. Accordingly, use of the term aortic aneurysm in this specification and claims is intended to relate to and mean both abdominal aortic aneurysms, thoracic aneurysms and related vessel diseases.

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Endovascular fastener applicator 50 has a delivery assembly 60 and a control assembly 140. Delivery assembly 60, as illustrated in FIG. 9, includes a tubular body, such as, for example, an outer sleeve 64, an elongate control 68, a delivery tube 72 and a drive assembly 76, each having a proximal and distal end relative to control assembly 140. Outer sleeve 64 defines a channel 65 and is adapted for insertion within aorta 124 (as shown in FIG. 10) and has an expandable portion 66 operatively connected at its distal end. Elongate control 68 is coaxially positioned within channel 65 of outer sleeve 64 and is operatively connected to expandable portion 66 at its distal end. Delivery tube 72 defines a channel 71 and is coaxially positioned within channel 65 of outer sleeve 64 and adapted for advancing a helical fastener 80 to the abdominal aortic aneurysm site. Drive assembly 76 is coaxially positioned within channel 71 of delivery tube 72 and adapted for advancing, in cooperation with delivery tube 72, and deploying helical fastener 80 into aortic graft 100 and aorta wall 132. It is contemplated that the components of the delivery assembly may be alternately oriented relative to each other, such as, for example, bi-axial, offset, etc. It is further contemplated that the components of delivery assembly 60 are flexible and may be constructed from a shape memory material.

Operation of endovascular fastener applicator 50 is controlled by control assembly 140. As shown in FIGS. 1 and 9, control assembly 50 includes outer sleeve push bar 146, expandable portion control 150, delivery tube push bar 148 and handle 144. Outer sleeve push bar 146 is operatively connected to the proximal end of outer sleeve 64 for regulating movement of outer sleeve 64. Expandable portion control 150 is operatively connected to the proximal end of elongate control 68, which in turn is connected to expandable portion 66. Correspondingly, expandable portion control 150 controls the expansible force AA (shown in FIG. 12) exerted by expandable portion 66 for supporting aortic graft 100 in contact with aortic wall 132. Outer sleeve push bar 146 may also be adapted to influence expansible force AA.

Delivery tube push bar 148 is operatively connected to the proximal end of

delivery tube 72 for regulating movement of delivery tube 72. Handle 144 is operatively connected to the proximal end of drive assembly 76, for controlling axial and rotational movement of drive assembly 76, described in detail below.

5 As shown in FIG. 9, drive assembly 76 includes a drive 78. Drive 78 at its distal end has a curved portion 79 oriented at substantially 90° to the longitudinal axis of outer sleeve 64 and delivery tube 72 (similarly shown in FIGS. 10 and 12). It is contemplated that the curved portion may be positioned at various angular orientations. Drive assembly 76 transmits rotational motion from its proximal end to its distal end and through its curved portion 79 to facilitate deployment of helical fasteners 80 into the
10 aortic graft 100 and aortic wall 132.

In one embodiment, as illustrated in FIGS. 5-8, helical fasteners 80 have a sharpened distal end 81 and a penetration limit end 82. Helical fastener 80 has an outer diameter 83 and an inner diameter 84. Outer diameter 84 facilitates penetration of sharpened distal end 81 into aortic graft 100 and aortic wall 132. The surface of inner
15 diameter 84 cooperatively engages drive assembly 76 and delivery tube 72 at their distal ends to facilitate loading of helical fastener 80 into endovascular fastener applicator 50. Preferably, inner diameter 84 and penetration limit end 82 have a rectangular configuration for cooperative engagement with drive assembly 76, drive assembly 76 also having a rectangular configuration at its distal end. Although a helical fastener is
20 disclosed it is contemplated that fastener 80 may have various configurations, such as, for example, cylindrical, triangular, etc. It is further contemplated that fasteners 80 are of the metallic fastener staple type and are preferably made from stainless steel but may be constructed from a polymeric material.

In the embodiment illustrated in FIG. 9, drive 78 is made from a shape memory alloy whereby drive 78 assumes the curved configuration of curved portion 79 upon
25 exiting delivery tube 72. Delivery tube 72 may also include an applicator head 73 at its distal end having a curved orientation to facilitate deployment of helical fasteners 80, as shown in FIGS. 14, 16 and 19. Helical fasteners 80, as shown in FIG. 3, are deployed

into aortic graft 100 and aortic wall 132 for fastening.

In an alternate embodiment, repair of abdominal aortic aneurysm 120, as shown in FIG. 10, proceeds by insertion of endovascular fastener applicator 50 into aorta 124 and advancing to the abdominal aortic aneurysm site by manipulation by a surgeon of control assembly 140. Endovascular fastener applicator 50 delivers aortic graft 100 to abdominal aortic aneurysm 120 by advancing the aortic graft 100 so that a sufficient portion of aortic graft 100 is brought in contact with aortic wall 132. Aortic graft 100 is a conventional tubular graft made of DACRON®, TEFLON® (polytetrafluoroethylene) and the like and is of a length sufficient to span the abdominal aortic aneurysm 120.

With reference to FIGS. 11-19, delivery assembly 60 and aortic graft 100 are delivered to the abdominal aneurysm site by manipulation of outer sleeve push bar 146, as shown by arrows A in FIG. 11. Aortic graft 100 is positioned at the abdominal aneurysm site. Expandable portion 66 is caused to expand, shown by arrows AA in FIG. 12, in response to cooperative manipulation of outer sleeve push bar 146 and elongate control 68. Outward radial force AA supports aortic graft 100 in contact with aortic wall 132. Expandable portion 66 facilitates fastening of aortic graft 100 with aortic wall 132 by deployment of helical fasteners 80. In this embodiment, expandable portion 66 includes support members 67 that define interstitial regions 70 therebetween. Helical fasteners 80 are deployed through interstitial regions 70 and into aortic graft 100. It is contemplated that helical fasteners 80 may be deployed at various locations about the circumference of aortic graft 100 relative to the number of support members 67 and spacing of interstitial regions 70.

Delivery tube push bar 148 is manipulated to axially advance delivery tube 72 within outer sleeve 64, as shown by arrows B in FIG. 13. At its distal end, delivery tube 72 has an applicator head 73 configured to have a substantially perpendicular orientation to the longitudinal axis of delivery tube 72. Drive 78 follows the substantially perpendicular orientation of delivery tube 72 to facilitate deployment of helical fasteners 80. It is contemplated that applicator head 73 may have various configurations and

orientations to facilitate deployment of helical fasteners 80.

With reference to FIG. 14, delivery tube 72 is advanced to a location where aortic graft 100 will be fastened to aortic wall 132. A loaded helical fastener 80 is oriented for deployment by applicator head 73, as shown by arrows C. Applicator head 73 is articu-
5 lable in a clockwise and a counter-clockwise direction about the inner surface of graft 100. The surface of inner diameter 84 and penetration limit end 82 of helical fastener 80 have a rectangular configuration for cooperative engagement with drive assembly 76, drive assembly 76 also having a rectangular configuration at its distal end (FIG. 17). It is contemplated that the remainder of drive assembly 76 may not be in
10 cooperative engagement with the surface of inner diameter 84. Helical fastener 80 has a substantially circular cross-section. It is envisioned that other cross-sectional configurations may be used that are suitable for fastening.

With reference to FIG. 15 and 16, handle 144 is manipulated to advance drive assembly 76. A torque is applied to handle 144 transmitting a rotational force from the proximal end to the distal end of drive assembly 76. The rectangular configuration of
15 drive assembly 76 cooperates with the rectangular configuration of the surface of inner diameter 84 causing rotational movement of helical fastener 80. The sharpened distal end 81 of helical fastener 80 contacts the interior wall 102 of aortic graft 100 thereby facilitating deployment of fastener 80 into aortic graft 100 and aortic wall 132. Helical
20 fastener 80 penetrates aortic graft 100 and aortic wall 132 to penetration limit end 82 thereby fastening aortic graft 100 to aortic wall 132.

In the embodiment shown in FIG. 19, delivery tube 72 cooperates with elongate control 68 at junction 69. Junction 69 facilitates rotation of delivery tube 72 and drive assembly 76 positioned coaxially therewithin, to a location for deployment of helical
25 fasteners 80, as shown in FIG. 19 by arrow D. Junction 69 rotates by manipulation of expandable portion control 150, as shown in FIG. 18. Delivery tube 72 is retracted from the fastening site and loaded with another helical fastener 80 for subsequent deployment at another location along the diameter of aortic graft 100. As many helical fasteners 80

may be deployed as are necessary to adequately fasten aortic graft 100 to aortic wall 132. Fastening in this manner prevents periprosthetic losses and accidental migration of aortic graft 100. It is contemplated that multiple helical fasteners 80 may be loaded into endovascular fastener applicator 50.

5 In another embodiment, as shown in FIGS. 20-27, endovascular fastener applicator 50 positions aortic graft 100 at the aneurysm site and in contact with aortic wall 132. Referring to FIG. 20 aortic graft 100 includes band 104 having anchor pads 107 implanted therewithin. As shown in FIG. 23, anchor pads 107 are implanted circumferentially about band 104. Band 104 may be fabricated from, such as, for example, polytetrafluoroethylene. Anchor pads 107, are implanted within band 104
10 corresponding to interstitial regions 70 located between support members 67 of expandable portion 66. Referring to FIG. 23, pads 107 have a substantially circular configuration. It is envisioned that the pads may have other configurations such as, for example, rectangular, elliptical, etc.

15 Anchor pads 107 cooperatively engage fastener guides 106 positioned at the distal end of drive assembly 76. Anchor pads 107 and fastener guides 106 cooperate to provide a guided deployment of helical fasteners 80 and facile release of drive assembly 76 from the aneurysm site. Referring to FIGS. 21 and 22, drive assembly 76 further includes multiple guide wires 77 releasably attached to fastener guides 106. Guide wires 77
20 facilitate guided travel of fasteners 80.

Referring back to FIG. 24, fastener guides 106 include anchor legs 108. Anchor legs 108 are resiliently biased so that upon deployment of helical fastener 80, anchor legs 108 are caused to collapse and release from band 104. Anchor legs 108 are connected to multiple guide wires 77 so that after collapse and release of anchor legs 108, multiple
25 guide wires 77 are retracted from the fastening site. Anchor pad 107 is retained within band 104 after helical fastener 80 is deployed.

As shown in FIG. 25, expandable portion 66 supports aortic graft 100 in contact with aortic wall 132. Applicator head 73 of delivery tube 72 is configured and

dimensioned to cooperate with inner diameter 84 to advance a helical fastener 80 over multiple guide wires 77, as shown by arrows E. As helical fastener 80 is deployed, anchor legs 108 are caused to collapse, shown by arrows F in FIG. 26. Delivery tube 72 causes rotational movement of helical fastener 80 and corresponding penetration of band 104, aortic graft 100 and aortic wall 132, facilitating fastening.

Delivery tube 72 is retracted subsequent to deployment of helical fastener 80 and multiple guide wire 77 is also retracted, as shown in FIG. 27, with helical fastener 80 in a deployed position. Delivery tube 72 is subsequently loaded with another helical fastener 80 for deployment from another of multiple guide wires 77. As many helical fasteners 80 may be deployed as are necessary to adequately fasten aortic graft 100 to aortic wall 132. It is contemplated that at least a portion of the fastener guides and/or guide wires may remain fixed to the prosthetic upon deployment of a fastener.

In another embodiment as shown in FIG. 28, control assembly 140 includes a handle 110 and a trigger 120 for controlling operation of endovascular fastener applicator 50. In this embodiment, handle 110 controls advancement of delivery tube 72 (not shown) and trigger 120 controls advancement of drive assembly 76 (not shown) and deployment of helical fasteners 80 (not shown).

In another embodiment, as illustrated in FIGS. 29-33, a plurality of helical fasteners 80 are loaded in endovascular fastener applicator 50 for deployment. As shown in FIG. 30, drive assembly 76 defines a channel 75 for accepting helical fasteners 80 (FIG. 31). In particular, penetration limit end 82 of helical fastener 80 slidably engages channel 75 providing a plurality of helical fasteners 80 for deployment, as shown in FIG. 29. Applicator head 73 of delivery tube 72 engages band 104, as shown in FIG. 32, and drive assembly 76 advances helical fasteners 80 to penetrate band 104, aortic graft 100 and aortic wall 132, shown by arrows G. As shown in FIG. 33, aortic graft 100 is fastened to aortic wall 132 of aorta 124 by helical fastener 80. After deployment of a helical fastener 80, delivery tube 72 is rotated to deploy another of the plurality of helical fasteners 80, consequently reloading is not required.

In another embodiment, as illustrated in FIGS. 34-51, expandable portion 66 is capable of moving between two extreme positions. A relaxed position, as shown in FIG. 35, and an expanded position, as shown in FIG. 34. In the embodiment illustrated in FIG. 34, expandable portion 66 includes support members 67 that define open interstitial regions 70.

As best shown in FIG. 36, outer sleeve 64 operatively engages with expandable portion 66 for controlling operation between the two extreme positions. Expandable portion 66 has an atraumatic head 200 attached to opening 210 defined at the distal end of expandable portion 66 and opening 212 defined at its proximal end for receiving applicator head 73 of delivery tube 72. Applicator head 73 includes ejection mount 250 for deployment of a plurality of helical fasteners 80 from drive assembly 76.

Ejection mount 250, as shown in FIG. 36, includes yoke 256 and ejection head 260. Yoke 256 engages penetration head 200 for coaxial positioning within expandable portion 66. Ejection head 260 is pivotally positioned within yoke 256. Ejection head 260 includes a cam divider 262 and a saw-toothed face 264. Ejection head 260 is capable of rotational movement relative to delivery tube 72 and pivotal movement between two extreme positions. A first extreme position is coaxial with delivery tube 72 and a second extreme position is perpendicular to the longitudinal axis of delivery tube 72 and in position to deploy a helical fastener 80.

With reference to FIGS. 37 and 38, drive assembly 76 includes distal drive 280, proximal drive 284, outer drive 285, ratchet assembly 286, spring 294 and washer 296. Distal drive 280 defines a slot 281 for receiving penetration limit end 82 for loading a plurality of helical fasteners 80. The plurality of helical fasteners 80 are spring loaded onto drive assembly 76 and separated from spring 294 by washer 296.

Distal drive 280 is operatively connected to ratchet assembly 286 which is operatively connected to proximal drive 284 and outer drive 285. Ratchet assembly 286 includes ratchet sleeve 287 which defines opening 288 for receipt of distal drive 280. Manipulation of proximal drive 284 causes movement of distal drive 280 to facilitate

deployment of helical fasteners 80. Ratchet sleeve 287 also defines opening 289 for receipt of proximal drive 284. Ratchet sleeve 287 is slidably received within ratchet retainer 290 for cooperative engagement with outer drive 285. Ratchet retainer 290 defines opening 291 for receiving ratchet arm 292.

5 As shown in FIGS. 39 and 40, ratchet arm 292 engages ejection head 260. Ratchet arm 292 is positioned within cam divider 262 in ejection head 260 and secured therein by set screw 298. It is contemplated that ratchet arm 292 is crimped in place within ejection head 260 and that no set screw is required. It is further contemplated that ratchet arm 292 may be fixed within ejection head 260 as is known by one skilled in the art. Manipulation of outer drive 285 engages ratchet retainer 290 and ratchet arm 292 causing pivotal movement of ejection head 260 relative to delivery tube 72.

10 As illustrated in FIGS. 41 and 42, delivery assembly 60 is positioned at the aneurysm site of abdominal aortic aneurysm 120. Aortic graft 100 is positioned for fastening to aortic wall 132 of aorta 124. Aortic graft 100 has band 104. Aortic graft 100 may also have gasket 105, as shown in FIG. 41, sewn to the outside diameter of aortic graft 100 to prevent leakage of fluid.

15 Expandable portion 66 is in a relaxed state, as shown in FIGS. 41 and 42. Aortic graft 100 is positioned at the abdominal aneurysm site and expandable portion 66 is caused to expand by axial motion of outer sleeve 64, shown by arrows I in FIG. 44 and by arrows H in FIG. 43, illustrating the outward force of support members 67 used to support aortic graft 100 in contact with aortic wall 132. Expandable portion 66 facilitates fastening of aortic graft 100 with aortic wall 132 for deployment of helical fasteners 80 by securing aortic graft 100 in contact with aortic wall 132. It is contemplated that helical fasteners 80 may be deployed from ejection mount 250 through interstitial regions 20 70 between support members 67. The helical fasteners 80 are deployed about the circumference of aortic graft 100 relative to the number of support members 67 and spacing of interstitial regions 70.

25 As shown in FIG. 45, drive assembly 76 is loaded with a plurality of helical

fasteners 80. Referring to FIG. 46, delivery tube 72 has an ejection arm 310 positioned at its distal end facilitating pivotal movement of ejection mount 250. An arm 292 functions as an ejection arm to ejection head 260. This provides extra holding force on the graft which pivots ejection head 260 positioned at its distal end. Ejection arm 310 includes a slider 312 received within a cam slot 300 defined by ejection head 260. Cam slot 300 further defines the relative movable limits of slider 312 and thus ejection arm 310.

Delivery tube 72 is manipulated advancing ejection arm 310 axially causing pivotal movement of ejection head 260, shown by arrow J, and positioning ejection head 260 for deployment of helical fasteners 80. Ejection head 260 is positioned in a substantially perpendicular orientation to the longitudinal axis of delivery tube 72.

It is contemplated that ejection arm 310 has alternate orientations for causing movement of ejection head 260. For example, in an alternate embodiment shown in FIG. 46A, ejection head 260 pivots within expandable portion 66 and is positioned at the center of expandable portion 66. Saw-toothed face 264 is positioned at a closer proximity to the inner surface of graft 100 for accurate deployment of a fastener. At the center position, ejection head 260 spans a diameter that expandable portion 66 supports aortic graft 100 in contact with aortic wall 132. In this embodiment, ejection arm 310 is fixed at a maximum angle relative to delivery tube 72.

Drive assembly 76 is manipulated so that ejection head 260 engages band 104 of aortic graft 100 for deployment of helical fasteners 80, as illustrated in FIG. 47. Outer drive 285 and proximal drive 284 are advanced, shown by arrows K. Ejection arm 292 correspondingly axially positions saw-tooth face 264 of ejection head 260 to contact band 104 of aortic graft 100, as shown by arrow L. Ejection arm 292 may also cause rotational movement of ejection head 260 and saw-tooth face 264 for engaging aortic graft 100.

With reference to FIG. 48, distal drive 280 advances and is rotated causing helical fasteners 80 to penetrate and fasten aortic graft 100 and aortic wall 132, as shown by arrow M.

As shown in FIG. 49, delivery tube 72 is manipulated so that ejection arm 310

pivotaly retracts ejection head 260 to a position substantially parallel to the longitudinal axis of delivery tube 72, as shown by arrows MM.

FIG. 50 illustrates a retracted ejection mount 250 subsequent to deployment of one of a plurality of helical fasteners 80. A rotational force is transmitted from the proximal end to the distal end of drive assembly 76, shown by arrows N, thereby driving and axially advancing another of the plurality of helical fasteners 80, shown by arrows P, for deployment by ejection head 260 at a new deployment site.

FIG. 51 shows ejection head 260 positioned in a substantially perpendicular orientation to the longitudinal axis of delivery tube 72(not shown). Ejection head 260 is rotated to a new deployment site to deploy another of the plurality of helical fasteners 80 (not shown). As many helical fasteners 80 may be deployed as are necessary to adequately fasten aortic graft 100 to aortic wall 132.

It will be understood that various modifications may be made to the embodiments disclosed herein. For example, while specific preferred embodiments of the endovascular fastener applicator have been described in detail, structures that perform substantially the same function in substantially the same way to achieve substantially the same result may also be used. For example, the expandable portion may include expanding wires for supporting a prostheses in contact with a vessel wall. Also the fastener guide may be implanted completely through the thickness of the aortic graft. Further, the helical fasteners may be constructed from various suitable materials or may embody one continuous fastener that is severable at the point of insertion. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments, those skilled in the art will envision other modifications within the scope and spirit of the present disclosure.

WHAT IS CLAIMED IS:

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1. An endovascular fastener applicator for endoluminally fastening a
prosthetic to a vessel with a fastener, the applicator comprising:

a tubular body configured for positioning within a vessel;

an expandable portion disposed adjacent a distal end of the tubular body
and being deployable to support a prosthetic in contact with an inner surface of a vessel;
and

a drive assembly for advancing a fastener into the prosthetic.

2. An endovascular fastener applicator as recited in claim 1, further
comprising a control assembly operatively connected to said drive assembly for
extracorporeal control of the applicator.

3. An endovascular fastener applicator as recited in claim 1, further
comprising a delivery tube being disposed for movement within the tubular body and
defining a channel for movement of the drive assembly therewithin, the delivery tube
being configured for advancing a fastener within the tubular body.

4. An endovascular fastener applicator as recited in claim 1, further comprising an elongate control positioned for movement within the tubular body, wherein the expandable portion is operatively connected to a distal end of the tubular body and a distal end of the elongate control, the tubular body and the elongate control being manipulable to facilitate support of the prosthetic in contact with an inner surface of a vessel.

5. An endovascular fastener applicator as recited in claim 4, wherein the elongate control is coaxially disposed with the tubular body.

6. An endovascular fastener applicator as recited in claim 3, wherein the delivery tube is coaxially disposed with the tubular body.

7. An endovascular fastener applicator as recited in claim 1, wherein the drive assembly is coaxially disposed with the tubular body.

8. An endovascular fastener applicator as recited in claim 1, wherein at least a portion of the applicator is fabricated from a shape memory material.

9. An endovascular fastener applicator as recited in claim 1, wherein the drive assembly includes a curved portion oriented at an angle of substantially 90° from a

longitudinal axis defined by the tubular body.

10. An endovascular fastener applicator as recited in claim 1, wherein the drive assembly is configured for axial and rotational motion.

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11. An endovascular fastener applicator as recited in claim 3, wherein the delivery tube includes an applicator head configured to facilitate deployment of a fastener.

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12. An endovascular fastener applicator as recited in claim 1, wherein the expandable portion includes support members that define open interstitial regions therebetween.

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13. An endovascular fastener applicator as recited in claim 12, wherein the support members comprise a plurality of flexible wires.

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14. An endovascular fastener applicator as recited in claim 12, wherein the support members comprise a plurality of flexible tapes.

15. An endovascular fastener applicator as recited in claim 11, wherein the applicator head has a substantially perpendicular orientation to a longitudinal axis

defined by the delivery tube.

16. An endovascular fastener applicator as recited in claim 1, wherein the drive assembly includes a drive rod having a rectangular cross-section, the drive rod cooperating with an inner diameter of a fastener whereby movement of the drive rod causes advancement of a fastener.

17. An endovascular fastener applicator as recited in claim 1, wherein the applicator is configured to deploy multiple fasteners.

18. An endovascular fastener applicator as recited in claim 1, wherein the drive assembly includes at least one fastener guide configured to guide advancement of a fastener, each fastener guide cooperates with a prosthetic for guiding advancement of a fastener.

19. An endovascular fastener applicator as recited in claim 2, wherein the control assembly includes a handle having a pistol-grip trigger configuration.

20. An endovascular fastener applicator as recited in claim 11, wherein the applicator head includes an ejection mount disposed for movement relative to a prosthetic and configured for deployment of a plurality of helical fasteners, the ejection

mount has an ejection head with a saw toothed face configured for engaging a prosthetic, facilitating uniform deployment of each fastener deployed.

21. An endovascular fastener applicator as recited in claim 20, further
5 including a ratchet assembly configured to facilitate movement of the ejection mount.

22. An endovascular fastener applicator system for repairing a damaged
portion of a vessel, the system comprising:

at least one helical fastener, each helical fastener having a penetrating end
10 and a limiting end;

a prosthetic; and

an endovascular fastener applicator including:

a tubular body configured for positioning within a vessel;

a delivery tube being disposed for movement within the tubular body and
15 configured for advancing each helical fastener within the tubular body, the delivery tube
including an applicator head adjacent a distal end thereof, the applicator head being
configured for deploying each helical fastener and having a substantially perpendicular
orientation relative to a longitudinal axis defined by the delivery tube;

an expandable portion being operatively connected adjacent the distal end
20 of the tubular body and including support members that define open interstitial regions,
the support members being configured to support the prosthetic in contact with an inner

surface of the vessel;

a drive assembly being disposed for axial and rotational movement within the delivery tube, the drive assembly including a drive rod configured to cooperate with the helical fastener for advancing the helical fastener and facilitating deployment thereof to the prosthetic; and

a control assembly operatively connected to the drive assembly for extracorporeal control of the applicator.

23. An endovascular fastener applicator system as recited in claim 22, wherein the applicator head is configured for engaging an interior portion of the prosthetic to facilitate uniform deployment of each helical fastener.

24. An endovascular fastener applicator system as recited in claim 22, wherein the drive rod has a cross-section corresponding to an interior cross-section defined by each helical fastener and in cooperation facilitates advancement and deployment of each helical fastener.

25. An endovascular fastener applicator system recited in claim 22, wherein the prosthetic includes an interior band having anchor pads circumferentially spaced about and implanted within the band, the pads corresponding to the open interstitial regions of the expandable portion, the drive assembly further including guide

wires being configured for guiding advancement of each helical fastener and having anchor legs adjacent a distal end of each of the guide wires, the anchor legs releasably engaging the anchor pads prior to deployment of each helical fastener and being retractable from the prosthetic upon deployment of each helical fastener.

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26. An endovascular fastener applicator system as recited in claim 22, wherein the applicator head includes an ejection mount being configured for deploying at least one helical fastener and movable relative to an interior circumference of the prosthetic for deploying each helical fastener, the ejection mount including an ejection head having a saw-toothed face for engaging the internal circumference of the prosthetic, the ejection head facilitating uniform deployment of each helical fastener.

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27. An endovascular fastener applicator system as recited in claim 26, further including a ratchet assembly being configured to facilitate movement of the ejection mount.

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28. A method for endoluminally repairing a damaged portion of a vessel, the method comprising the steps of:

providing an endovascular fastener applicator for endoluminally fastening a prosthetic to a vessel with a fastener, the applicator including: a tubular body configured for positioning within a vessel, an expandable portion disposed adjacent a

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distal end of the tubular body and being deployable for supporting a prosthetic in contact with an inner surface of a vessel, and a drive assembly for advancing a fastener into a prosthetic;

5 expanding the expandable portion adjacent an inner surface of the vessel to facilitate support of a prosthetic in contact with a vessel;

 advancing a fastener with the drive assembly to a site for deployment of the fastener; and

 deploying the fastener with the drive assembly to penetrate the prosthetic.

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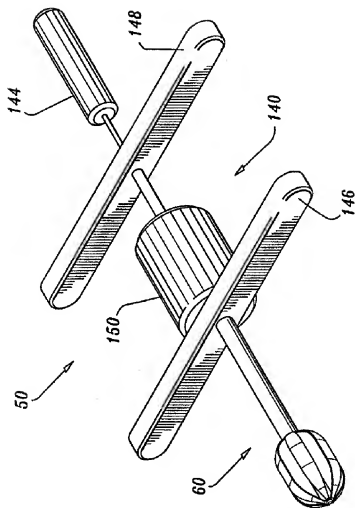
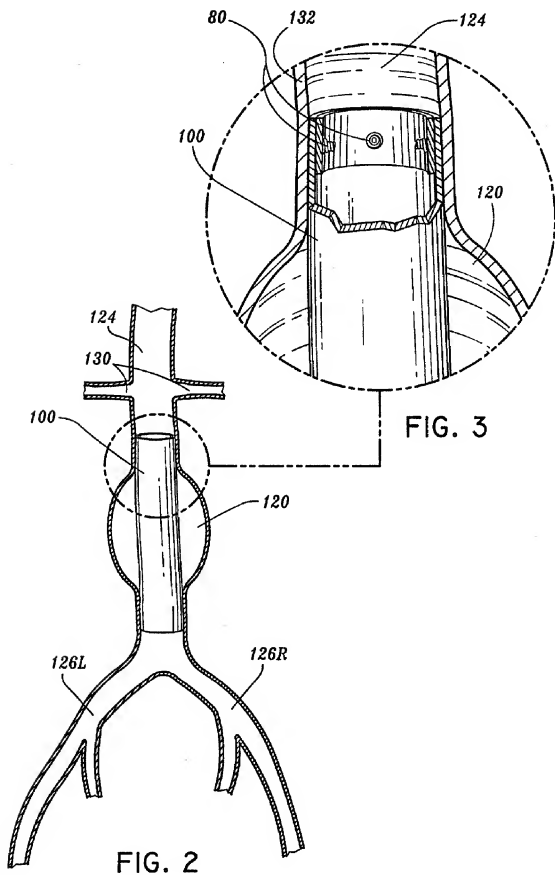


FIG. 1

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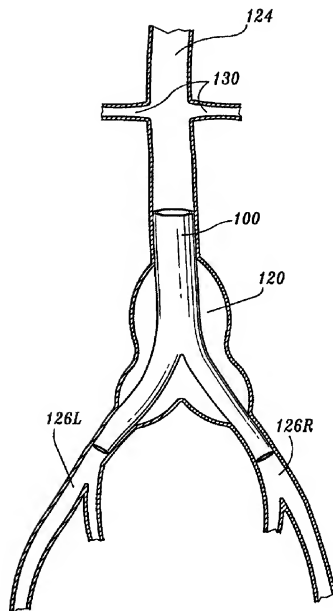


FIG. 4

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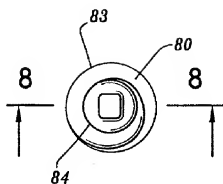


FIG. 7

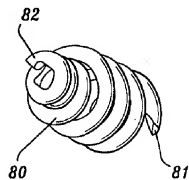


FIG. 5

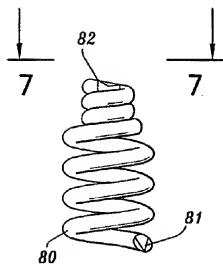


FIG. 6

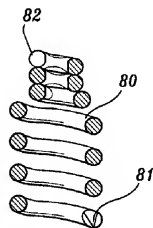


FIG. 8

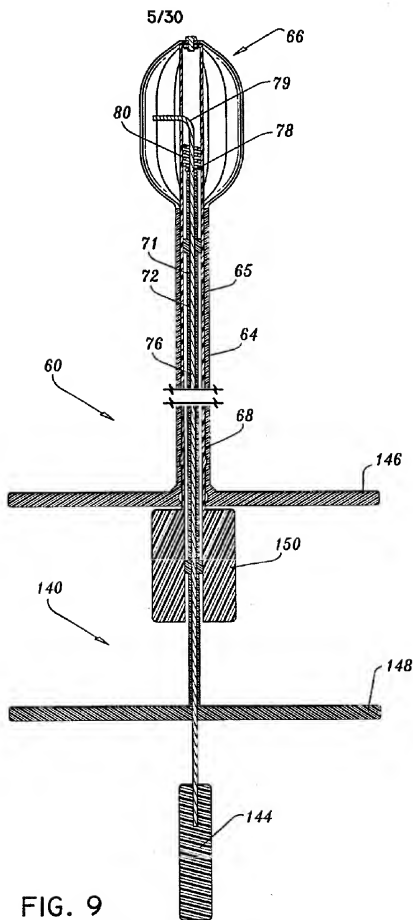


FIG. 9

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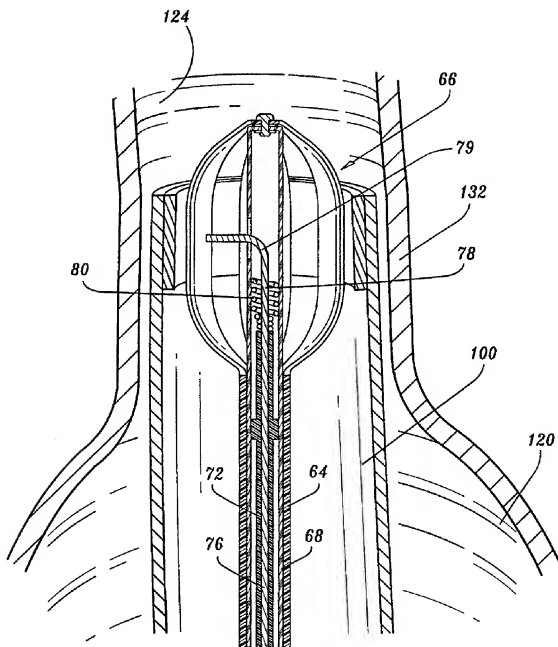
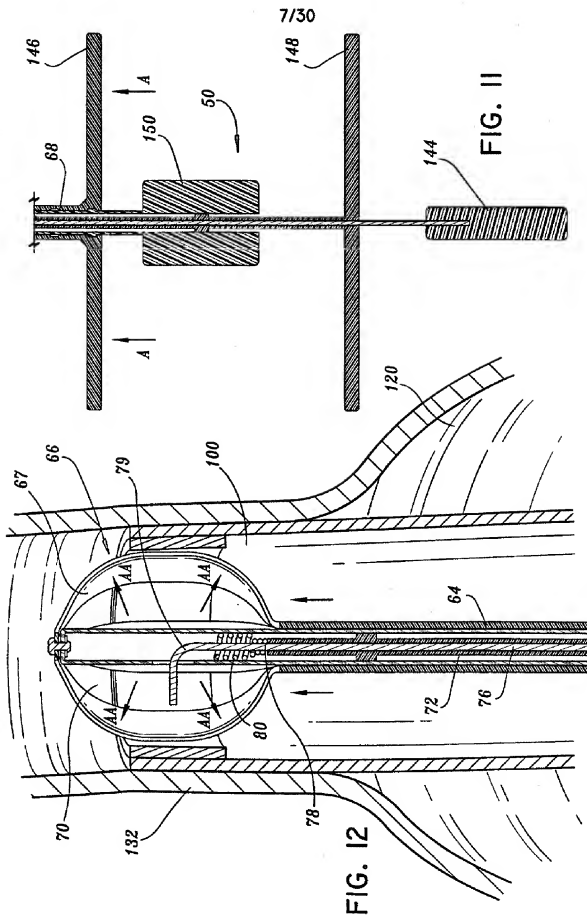
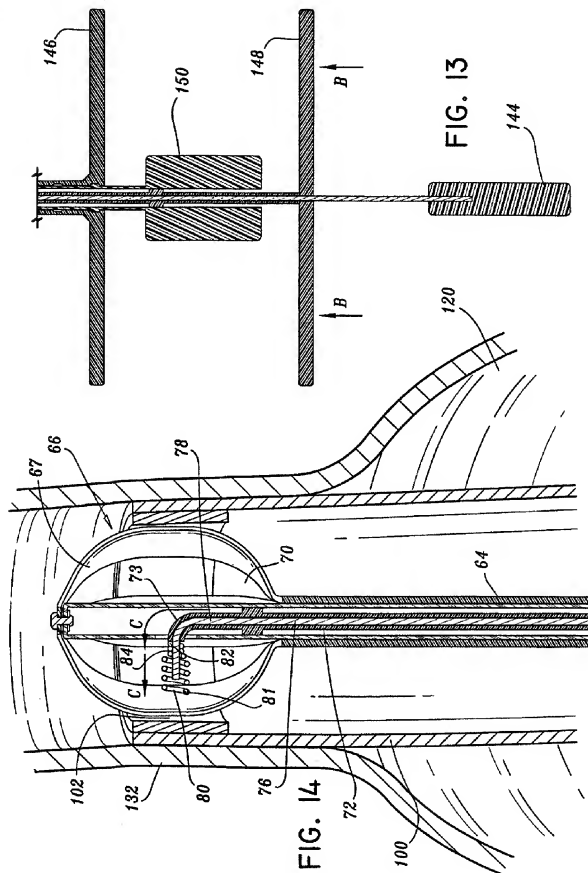


FIG. 10



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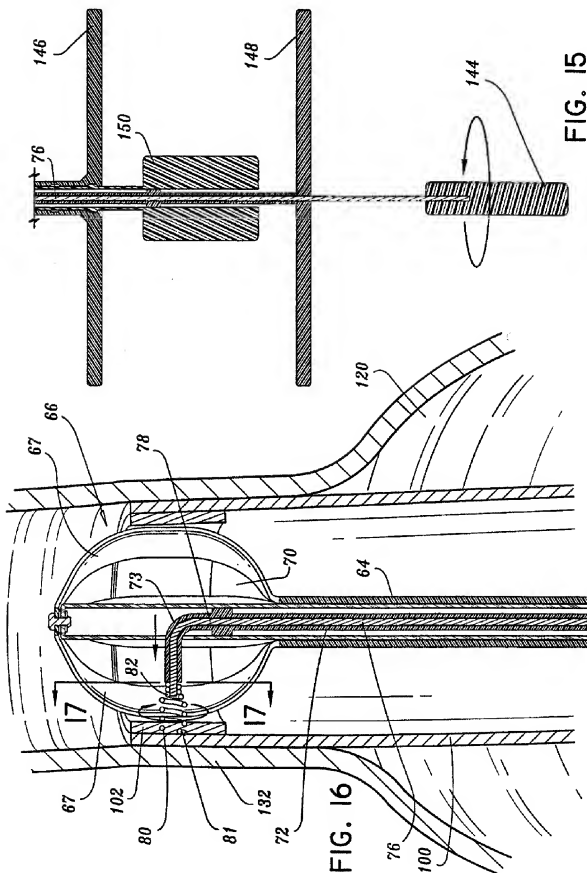


FIG. 16

FIG. 15

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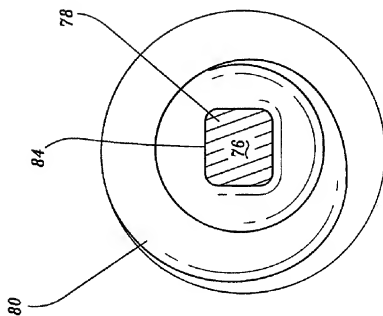


FIG. 17

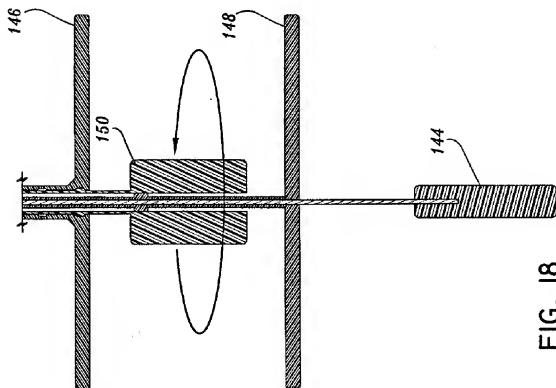


FIG. 18

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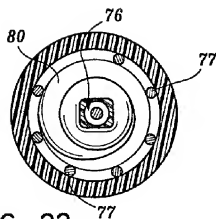


FIG. 22

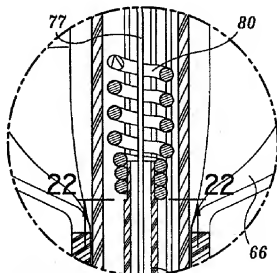


FIG. 21

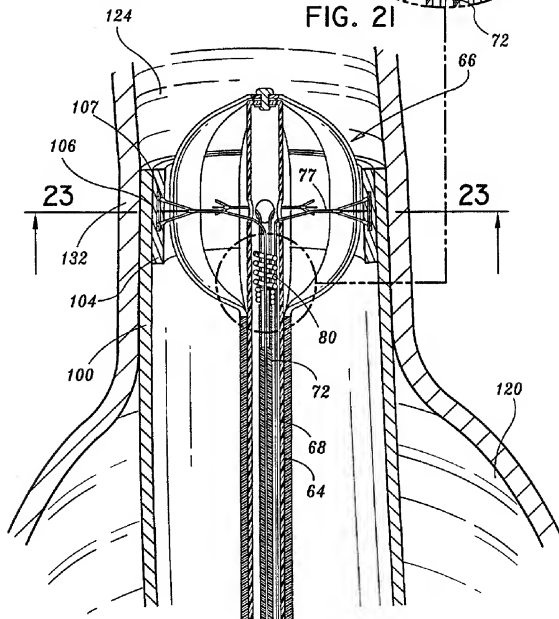


FIG. 20

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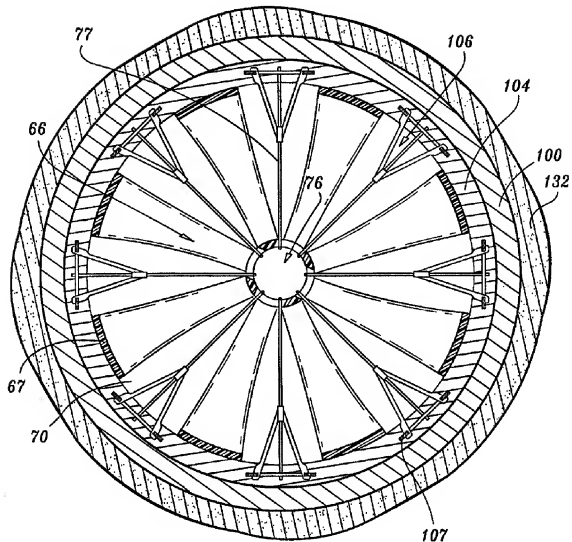


FIG. 23

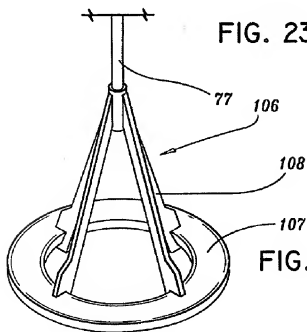


FIG. 24

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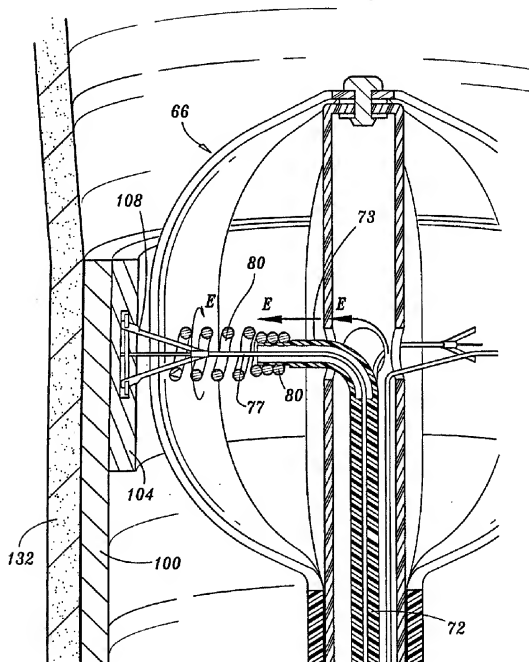


FIG. 25

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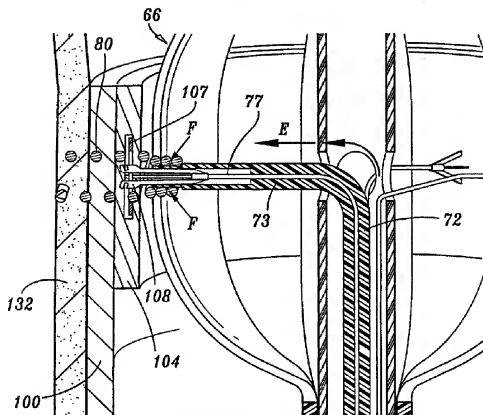


FIG. 26

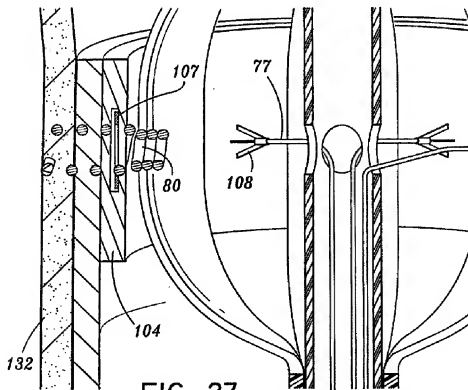


FIG. 27

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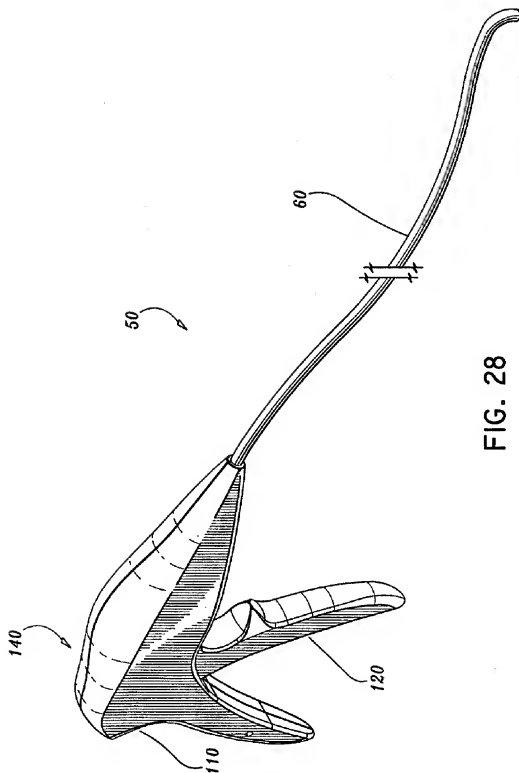


FIG. 28

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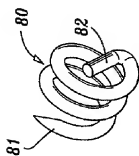


FIG. 31

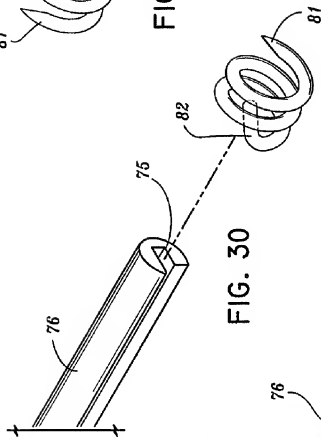


FIG. 30

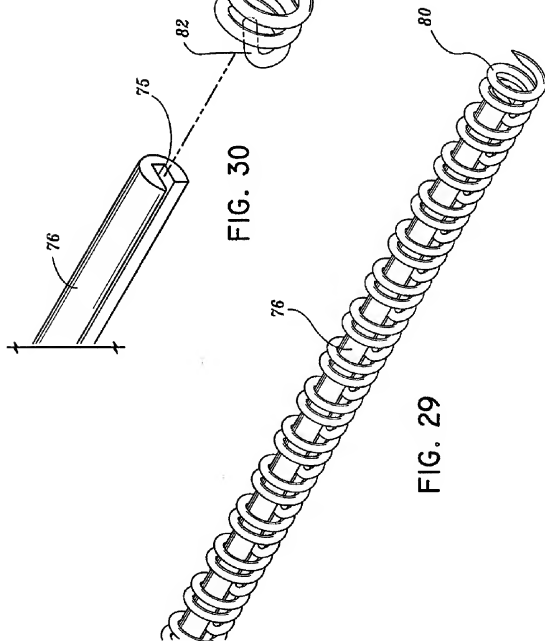


FIG. 29

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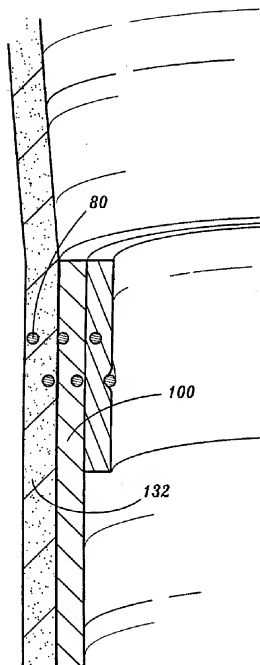


FIG. 33

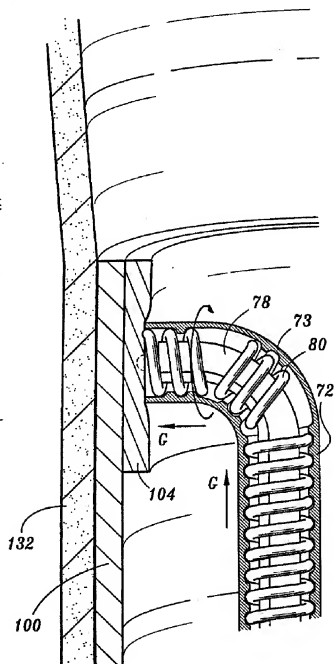
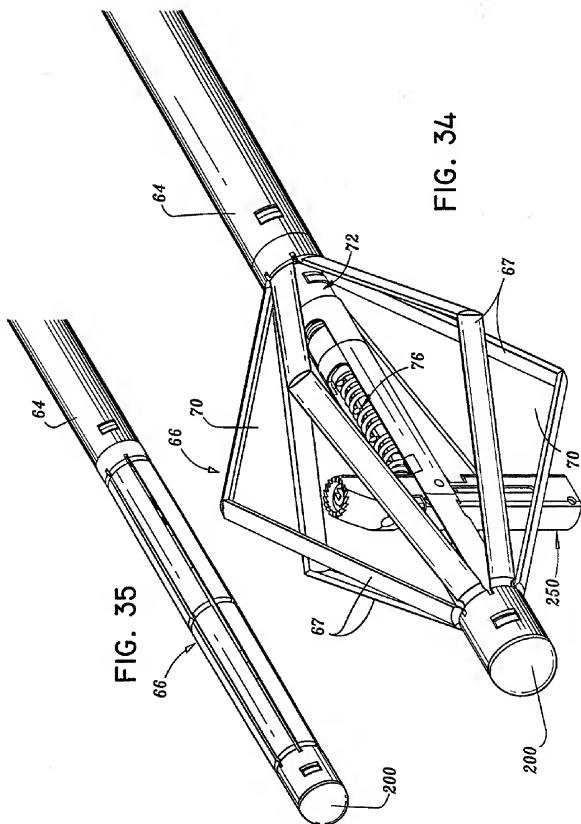


FIG. 32

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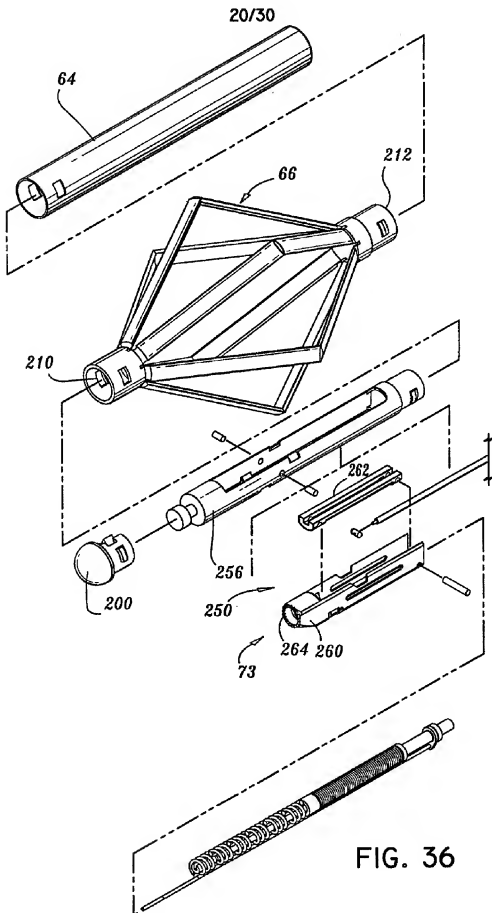


FIG. 36

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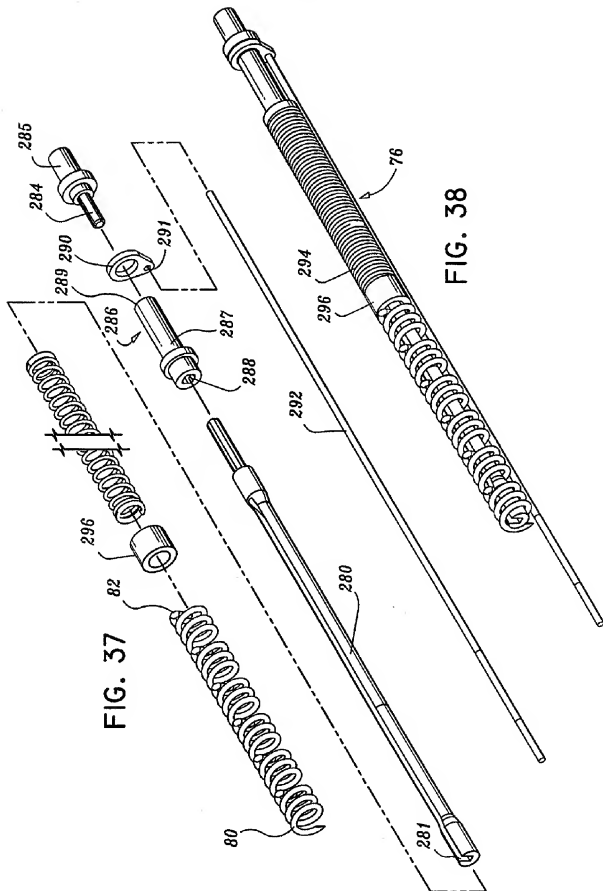


FIG. 38

FIG. 37

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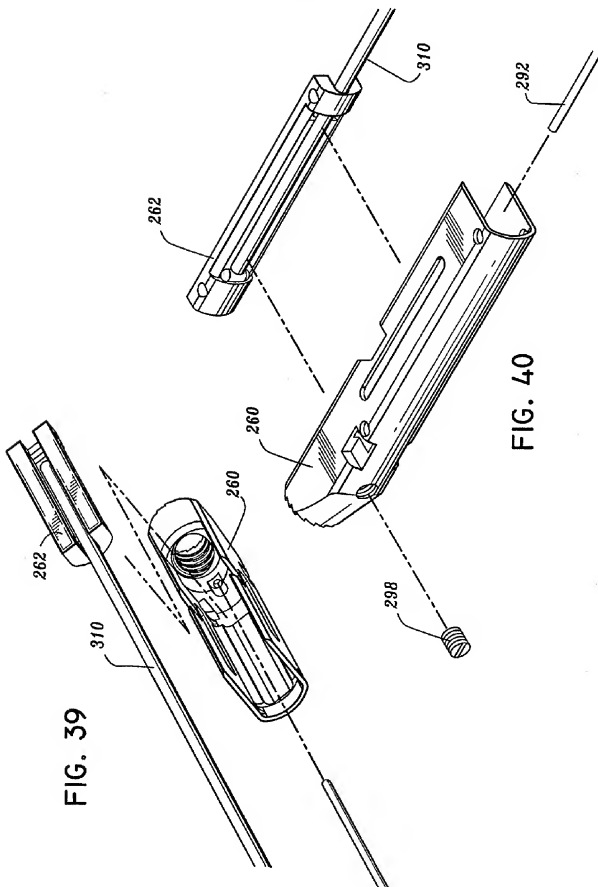


FIG. 39

FIG. 40

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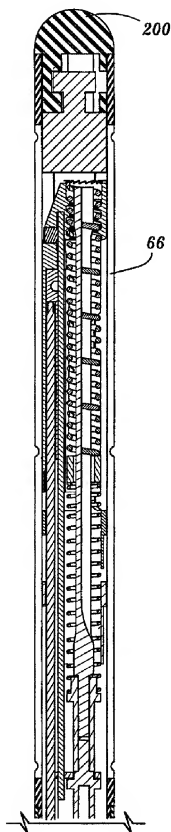


FIG. 42

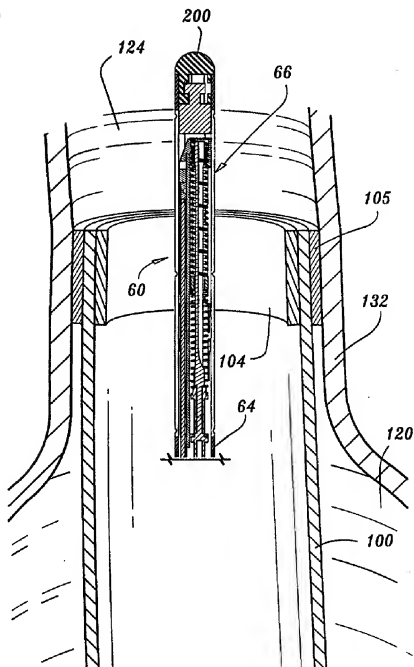
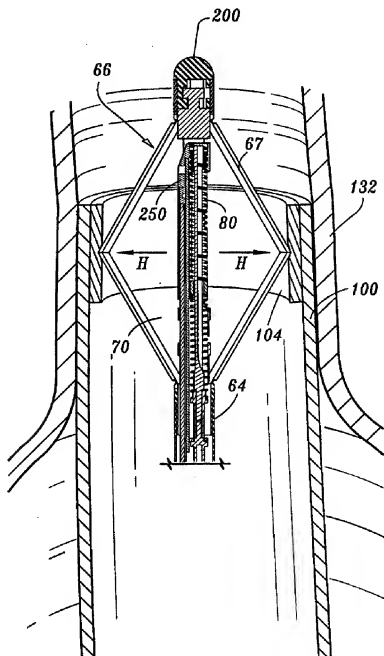
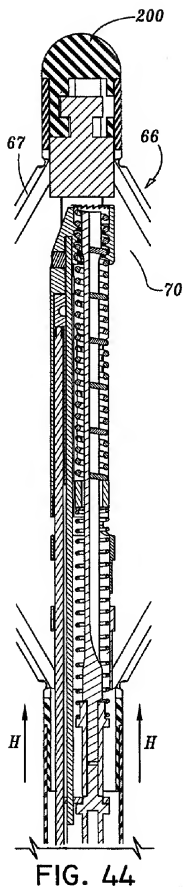


FIG. 41

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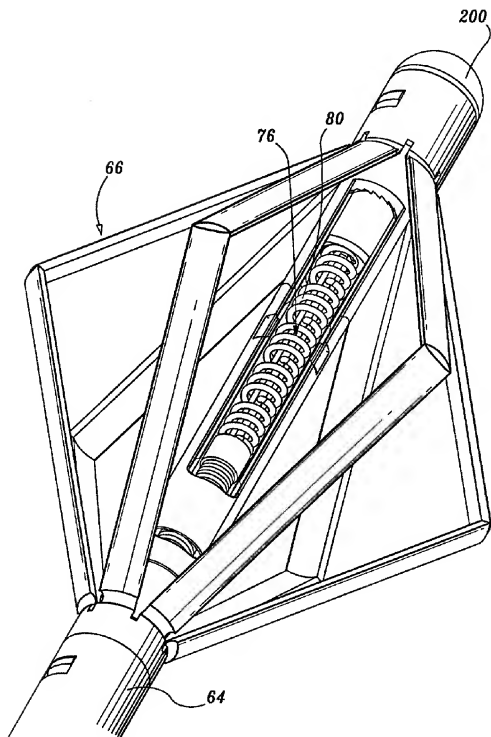


FIG. 45

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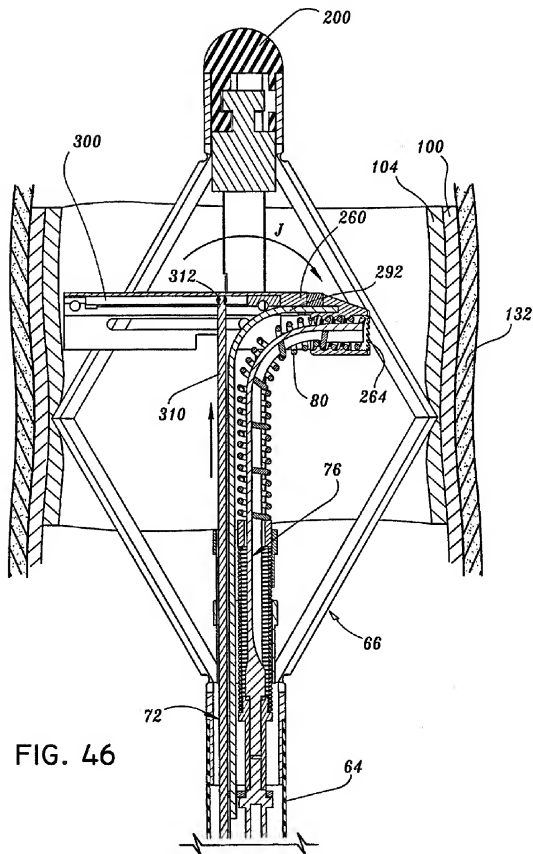


FIG. 46

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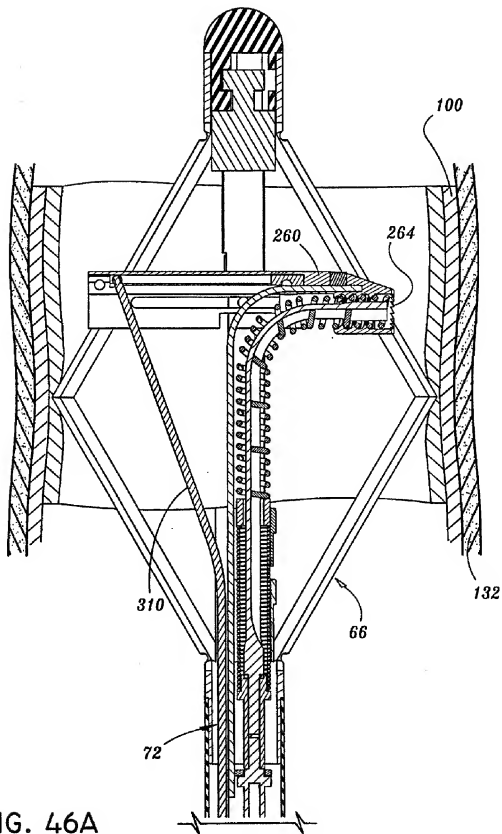


FIG. 46A

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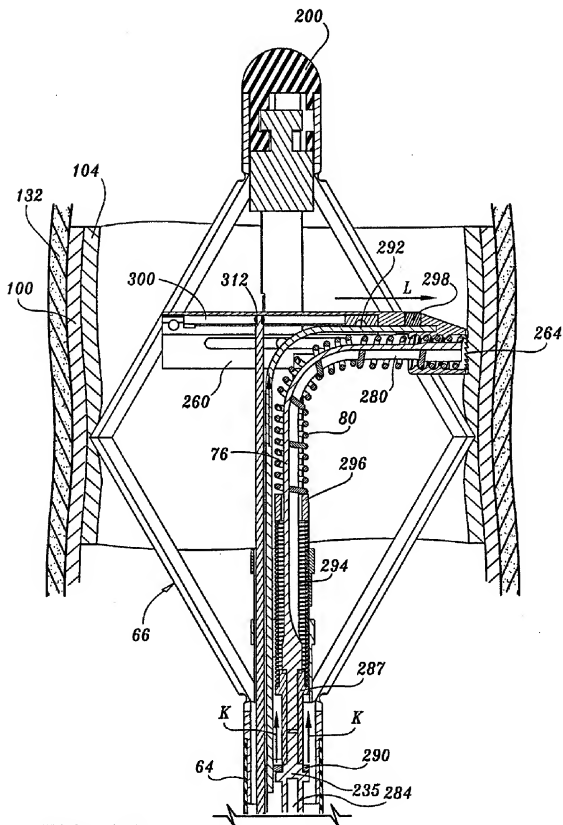


FIG. 47

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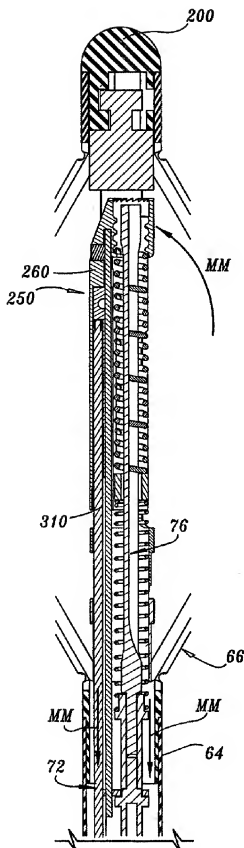


FIG. 49

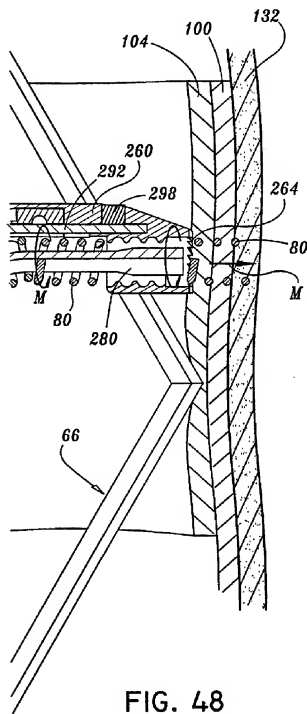


FIG. 48

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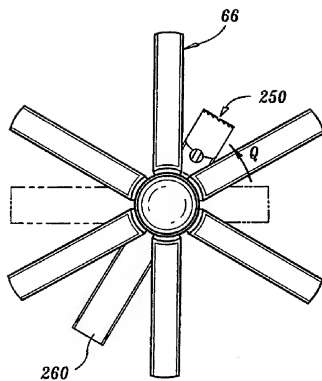


FIG. 51

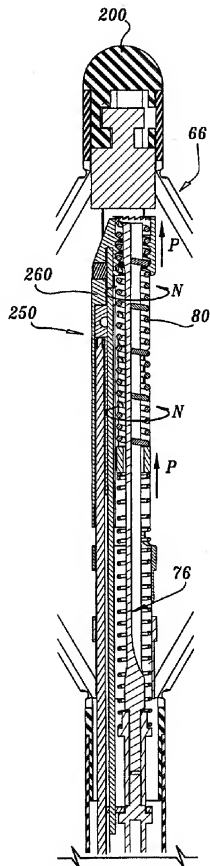


FIG. 50



Espacenet

Bibliographic data: CN 1019461 (B)

DEVICE FOR CONVEYING THIN AND LONG UNITS

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Inventor(s): AOYAMA YOSHITAKA [JP] ±
Applicant(s): YOSHITAKA AOYAMA [JP] ±
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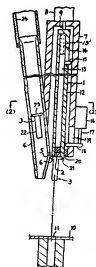
说明书页数:

附图页数:

[54] 发明名称 细长零件的输送装置

[57] 摘要

一种细长零件如螺栓的输送装置,具有一条当把细长零件固定在其端部时能被送进和撤回的输送杆,以及一条把细长零件送至处于预备位置的输送杆附近的一个位置,所述输送杆和输送管之间呈锐角,该输送装置的结构特征使其可以顺利可靠地将细长零件从输送管移至输送杆。



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1

权 利 要 求 书

1. 一种细长零件的输送装置, 用于将细长零件送至预定地点, 其特征在于它包括:

一输送杆, 其一端有一个用磁力固定细长零件的装置;

安装上述输送杆的装置, 用于在间隔开上述预定地点的一个端回位置和临近上述预定地点的一个第二位置之间往复运动;

一条输送管, 该输送管在上述输送杆的端回位置临近上述输送杆的上述一端处有一个下端开口, 输送管的该下端开口的轴线与上述输送杆往复运动的路径成锐角; 以及

向上述输送管的上部供应细长零件的装置, 其中, 所述细长零件通过上述输送管自由落下, 并由上述输送管的上述下端开口提供供给在输送杆一端用磁力固定细长零件的装置, 使所述细长零件的轴线与所述输送杆往复运动路径的轴线成锐角。

2. 按照权利要求1所述的装置, 其特征在于: 所述输送管下端的内表面是一凸轮表面, 用于修正细长零件的倾角。

3. 按照权利要求1所述的装置, 其特征在于: 所述输送管下端的内表面是一凸轮表面, 用于修正细长零件的倾角, 而且用于向细长零件的头部施加一个制动力。

4. 按照权利要求1所述的装置, 其特征在于: 所述输送管的所述下端是开口的, 用于在所述端回位置时, 在所述输送杆的所述一端供给细长零件, 在所述输送杆的与所述输送管的相对的一侧安置一块磁铁, 用于增强对细长零件的从所述输送管向着所述输送杆的所述一端的磁性吸力。

5. 一种带有头部的细长零件的输送装置, 用于将带有头部的细长零件送至预定的地点, 其特征在于它具有:

一输送杆, 其一端有一个用磁力固定带头部的细长零件的装置;

安装上述输送杆的装置, 用于在间隔开上述预定地点的一个端回位置和临近上述预定地点的一个第二位置之间往复运动;

一条与所述输送杆的上述往复运动路径成锐角放置的输送管, 该输送管的一个下部开口端在上述端回位置时位于所述输送杆所述一端的附近,

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一个夹持件, 可以在一个封住所述输送管以修正带头部的细长零件的姿态的向前位置和从所述输送管的所述开口端端回的一个第二位置之间移动; 以及

移动上述夹持件的装置, 其中, 所述带头部的细长零件通过所述输送管自由落下, 并以正确的姿态送至所述输送杆一端的用磁力固定带头部的细长零件的装置。

5. 按照权利要求5所述的装置, 其特征在于: 所述输送管和所述输送杆倾斜放置, 所述输送管的开口下端位于处在所述端回位置的所述输送杆所述一端的下方。

7. 按照权利要求5所述的装置, 其特征在于: 所述输送管的所述下端在处于所述端回位置的所述输送杆的所述一端的一侧是开口的, 在所述输送杆与所述输送管相对的一个第二侧放置一块磁铁, 当所述夹持件移到所述第二位置时, 所述细长零件受所述磁铁的吸力输送到输送杆的所述一端。

8. 按照权利要求5所述的装置, 其特征在于: 在所述输送杆的所述一端设有一止动件, 使带头部的细长零件止动。

9. 按照权利要求5所述的装置, 其特征在于: 所述输送杆是一个上螺母器。

10. 按照权利要求5所述的装置, 其特征在于: 在所述输送管的下端设有一个驱动装置, 用于将固定在所述端部的带头部的细长零件移送至所述输送杆。

11. 按照权利要求5所述的装置, 其特征在于: 所述输送管的下端设有一截获通过所述输送管下落的带头部的细长零件的止动部件。

本发明涉及把细长零件如螺钉输送到预定地点的装置。

在英国专利GB-1406530等现有技术文件中曾提出在输送杆的前端夹持一细长零件并将其输送到预定地点的机构, 采用过在所述输送杆上安装夹盘的形式, 将细长零件导向输送杆前端的方法, 曾采用垂直设置在输送杆上的一种导槽以便使细长零件沿导槽移动。

当采用上述夹盘机构时, 夹盘机构的任何故障都可能导致细长零件在输送杆前进时碰到其它部件而

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使细长零件的前端下落。当夹盘的夹爪精度不够时就会发生上述情况。

另外,当安装上述导槽时,必须有足够大的安装空间,因而可用空间有限时往往不能采用这样的导槽。

然而最重要的问题在于,细长零件应该迅速而可靠地夹持在输送杆的前端。至于零件的姿态控制,不暂时停止细长零件就很难使其通过一输送管而精确地移向输送杆的前端,这有时会引起零件不能正确地夹持在输送管前端的情况。

为了解决上述问题,本发明的输送细长零件的装置,采用一输送杆靠产生的磁力将细长零件夹持在其前端并将细长零件送往预定点。所述装置具有一细长零件的输送管与上述输送杆的行程方向呈锐角设置,所述输送管的端部靠所述输送杆的前端。细长零件由磁力从输送管的端部送到输送杆的前端。

在本发明的一推荐实施例中装有一磁铁从输送杆之外施加磁力以使将细长零件的上部迅速有力地送到前端。

为了便于细长零件顺利送往输送杆,也可增设一修正凸轮面以便修正细长零件在输送管端部附近的倾角。

如果细长零件有一头部,那么需增设一制动凸轮面,以便在细长零件通过输送管的最后阶段可减小输送速度,从而可靠地将其送至输送杆。

本发明的另一种形式是一种在输送杆装置前端夹持带头部的细长零件并将其送至预定点的装置,该装置具有一与输送杆装置的行程方向呈锐角设置的输送管,该输送管的端部设置在上述输送杆装置的前端附近,所述输送管端部的一夹持件可被送至和缩回以便修正细长零件的姿态。细长零件由夹持件暂时锁固。当夹持件缩回时,细长零件就被送回输送杆装置的前端。

在本发明的一推荐实施例中,输送管被调整成倾斜状态,使输送管位于输送杆装置的上方。

当暂时紧固在输送管端部的细长零件被送回输送杆装置时,利用其自身重力使其自由下落。

为了将细长零件从输送管端部送回输送杆装置,也可向细长零件施加磁力。

输送杆装置具有一输送杆,其前端有一止动件,止动件外侧有一磁铁。在工作中,输送杆的送进行

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程开始时,细长零件的头部由磁铁控制并止动件正确定位。

输送杆装置有一个上螺母器。如果细长零件是一带头部的螺栓时,头都由上螺母器接合并紧固,以便将其送往一配合件的螺孔。

设有一驱动装置以便将由输送管紧固的细长零件送往输送杆装置;细长零件就是被该驱动装置强制送往输送杆装置的。

捕获下落细长零件的一止动装置设置在输送管端部,因此,可以实行止动件的运动控制和夹持件姿态保持两种作用。

现对照以下附图对本发明进行详细描述:

图1是一纵剖面图;

图2是沿图1中(2)-(2)线的剖面图;

图3是一侧视图;

图4、5和6是一纵剖面图;

图7是沿图8中(7)-(7)线的剖面图;

图8是一前视图;

图9是一纵剖面图;

图10是沿图9中00-00线的剖面图;

图11是一纵剖面图;

图12是沿图11中02-02线的剖面图;

图13是沿图11中03-03线的剖面图;

图14是一立体图;

图15是一局部剖视图;

图16是沿图15中00-00线的剖面图;

图17是一局部剖视图;

图18是一纵剖面图;

图19是一局部横剖面图;

图20是一纵剖面图。

首先描述图1和2中所示的第一实施例。在可被送进和缩回的输送杆1的前端装有一磁铁(永久磁铁)2,因而如虚线所示,细长零件3可被磁力吸住。如图所示,一细长零件3可从其中穿过的输送管4与输送杆1的行程方向呈锐角安装,其端部靠靠输送杆的前端6。

输送杆1装在套筒7中,可由一气缸8送进和缩回,气缸8接在套筒7的上端,其活塞杆9与输送杆1相连。当输送杆1前进直至细长零件3靠近一配合件10的孔11时,必须去掉作用在细长零件3上的磁力,因此,在磁铁2必须设计成是可以缩回的。

具体来说,输送杆1由一空心轴12和一个可在

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空心轴中滑动的内轴13组成。磁铁2被固定(例如,粘接)在内轴13的下部,空心轴12有一在行程方向上延伸的长孔14,如图所示,一固定在内轴13上的控制销15穿入长孔14中,在空心轴12中装有一盘簧13',其弹力使控制销15抵住长孔14的下端。在这种状态下,输送杆1的前端6碰定了一个空心轴12的端面与磁铁2相齐平的平面,如图中所示。

一气缸16固定在套筒7的下部侧面,其活塞杆17上装有一锁紧件18,套筒7也有一个在行程方向上延伸的长孔19,锁紧件18通过该长孔穿入套筒7,控制销15和锁紧件18的相对位置使得控制销15当输送杆1完成其预定行程时恰在锁紧件18跟前。

如图2所示,局部除去套筒7的壁而焊接着输送管4。另外,如图所示,由于输送杆有一个基本呈圆形的横截面,所以设有一防转件20(图1),输送杆1的前端6设有一凸起21用作止动器,从而使通过输送杆1的细长零件3可以正确定位。图中所示的细长零件3是一个螺柱,有一环状螺纹部分22和一圆形凸缘的头部23,图中略去了头部上的焊接用的凸起。输送管4一端接有聚氢乙烷或类似材料制成的输送软管24,另一端接着零件输送机(未画)。

在图1所示状态下,输送杆1处于其端部的极限位置,为零件下落做好了准备。当实线所示的头部23下落直接接近输送管4的端部时,磁铁2的磁力使细长零件3的上部移向右方直至头部23抵住凸起21为止,因而靠磁力夹持在输送杆1的前端,如虚线所示,接着输送杆1在气缸16的作用下前进到靠近配合孔10的孔11前方或者使细长零件3进入所述孔11,此时输送杆1的进给运动停止,控制销15位于索紧锁紧件18的跟前,然后,气缸16使其活塞杆17缩回,这一位移通过控制销15和内轴13传递到磁铁2,使磁铁2与头部23分开,因此,作用在细长零件3上的磁力随即消失,使细长零件落入孔11;这样便完成了零件的输送。

除了使用永久磁铁外,还有各种把磁力作用于输送杆前端的装置。例如,可以使用图3所示的电磁铁。在图3所示系统中,输送杆1穿过一圈线圈25,因而当输送杆1进给一预定距离时切断线圈电路即可消除磁力。

在图4所示的改进实施例中,为了增大细长零件趋向右方的力,磁铁(永久磁铁)26装在输送杆前端6的外侧。具体来说,磁铁26嵌在焊接于套筒7的

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一块罩板27内。

在图5所示的改进实施例中,磁铁(永久磁铁)28装在输送杆1凸起21的外侧,该磁铁28嵌在由螺栓30固定在内轴13上的一块滑板29内,螺栓30穿过长孔19,为了堵回内轴13,可采用类似于图1所示的系统。因此,由磁铁28吸住的细长零件被磁力固定在输送杆1的前端6而送往预定地点,然后缩回磁铁28使细长零件下落。此外,虽然在图5中内轴13上未装磁铁,但是如果装上磁铁,那么将会改善细长零件的定位。

现在讲述图6—10所示的改进实施例,但是以下说明将只侧重于与前述实施例不同之处。本实施例中最重要的零件是一凸轮件31,凸轮件31与输送管4相连接或者在输送管4上用堆焊形成。凸轮件31的作用是使细长零件3的前端6为修正的目的而向右移动以便于细长零件移向前端6,其另一作用是如零件有一头部,则在其头部制动细长零件以降低其速度,使其更可靠地移向前端6。

如图7和10所示,凸轮件31具有槽形横截面,凸轮面由一大曲率的第一凸轮面部分32和一个近于直线的第二凸轮面部分33,上述第一和第二凸轮面部分光滑地连接在一起。如图10所示,输送杆1的前端呈一侧开口的锥形,与槽形横截面的凸轮件31一起完全包住细长零件3的上部并确定了零件行程的路径。

如果沿输送管4下行的细长零件3与输送管4共轴而不是倾斜于输送管4的轴线,则细长零件3前进时不碰触凸轮面部分32,如图6中双点划线4所示状态并由另一凸轮面部分33作最小的姿态修正,这样,细长零件就被磁力吸引并固定于输送杆的前端6,另一方面,如果细长零件3倾斜下行,则它首先由凸轮面部分32作较大的姿态修正,然后由磁力吸引,当如图10所示具有头部23时,头部23与凸轮面部分32有力接触,所产生的摩擦力用来制动细长零件3,因此,细长零件3的下行速度减小,因而可靠地移向前端6。

如图6所示,凸起21伸出一连续的支承部分34,用于控制细长零件3,防止它歪向侧转,所述支承部分的前端可与螺纹部分22接触,也可与其分开一微小的间隙。尤其是当细长零件3有力地移向前端6时,惯性力容易使细长零件3的下面逆时针旋转一个很大的量,但是,支承部分34减小了这个侧转运动,使其更可靠地贴在前端6上。在图6所示的情形下,由于

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输送杆1倾斜,在输送杆1向前运动期间,支承部分34也正在发挥作用。另外,当磁力消失,输送杆停止在虚线所示位置上时,细长零件3绕支承部分34的前端逆时针旋转,同时摩擦上述前端;如图所示以这种方式落入孔11中。图6中标号35是一点焊的固定电极,图中未画与其相对的活动电极。

按照本发明,细长零件靠磁力固定在输送杆的前端,细长零件的输送管与输送杆呈锐角设置,所述输送管的端部靠近输送杆的前端设置;因此,达到输送管端部的细长零件可迅速可靠地移向相邻输送杆的前端,以很高的精度实现细长零件在输送杆前端的磁力固定。

由于在输送杆前端的外侧设置了磁铁,因而可以增大作用在细长零件上的移送吸引力,从而可以增加移送速度并保证可靠的移送。

由于输送管前端的内表面制有一凸轮,所以可修正细长零件的倾角以减少零件移向输送杆前端时整个零件的运动量。

在细长零件上具有头部的情况下,头部与凸轮面有力接触以减小零件的移送速度,从而也减小其功能,所以能够使零件上部方便而精确地移向输送杆的前端。

由于上述特殊效果,本发明可以解决夹盖和安装间隔等问题。

现在讲述图11至14所示的适用于带有头部的细长零件的一个实施例。本实施例中的带有头部的细长零件(以下简称细长零件)是如图所示的一种磁性,由一头部42和一杆部43构成,输送杆装置为图中所示输送杆44。

可被送进和端回的输送杆44的形状如图14所示,上面装有推头头部的止动件45。在图中所示的情况下,做成U形框架以便更稳定地固定头部42,所述框架具有相对的两壁46和一开口部分47。导入细长零件41的输送管48与输送杆44行程的方向呈锐角设置,其端部49在输送杆前端50附近设置。一短管51焊接于输送管48的前端,形成端部49,短管51的右侧,即与输送杆44的前端50配合工作的那一侧在图中表示为一开口部分52,在该开口中有一夹持件53,因而夹持件53可被送进和端回;因此,已从输送管48中下来的磁性41如图所示被锁定在端部49内表面和夹持件53间的一狭窄处,形成了一种所谓暂时锁定状态。

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送进和端回夹持件53的方法如图12所示,一气缸57固定在托架56上,托架则固定在下面还要详述的一套筒55上,其活塞杆58与夹持件53相连。

输送杆44装在一套筒55中并可被一气缸60送进和端回,气缸59装在套筒55的上端,其活塞杆与输送杆44相接,一磁铁(永久磁铁)61装在止动件的外侧以便把处于图11所示位置的磁性41移至输送杆44。当输送杆44被送进直至磁性41靠近一配合件62的孔63为止时,必须去消作用在磁性41上的磁力。为此,磁铁61被设计成可端回的,也就是说,磁铁61嵌在一滑动件64内,滑动件64可相对于输送杆44向上移动,从而使磁铁61与止动件45间隔开来,这样就去掉了作用在头部的磁力。为了实现上述动作,输送杆44是由一空心轴65和一可在空心轴65内滑动的内轴66构成的,滑动件64由磁性67固定在内轴66上,固定磁性67穿过空心轴65上形成并在行程方向上延伸的长孔68。

空心轴65上具有行程方向上延伸的长孔69,固定在内轴66上的一控制销70伸入其中,一叠套71装在空心轴65内,迫使控制销70抵住长孔69的下端,一气缸72固定在套筒55下部的筒状面区域,其活塞杆上装有一锁紧件74,该锁紧件74通过套筒55上的行程方向上的长孔75伸入套筒55内,控制销70和锁紧件74有下述的相对位置,当输送杆44完成其预定的行程时,控制销70恰在紧锁紧件74的前方。

如图11所示,输送管48和套筒55在76处焊接在一起,两者间形成锐角,输送管48就这样倾斜设置在输送杆44的上方。换言之,如图11所示输送管48倾斜设置在输送杆44的左方。另外,在内轴66的前端处装有一磁铁(永久磁铁)77以增加磁性41向输送杆前端50的磁力,但是,根据需要而定也可以不装,此外,一输送软管78和输送管48相接。

如图11中虚线所示,当磁性41沿输送管48下行时,其头部42在端部49的内表面和夹持件53间被截住,形成了图中实线所示磁性41的暂时锁固状态。这种暂时锁固提供了预定的定位,然后,夹持件53端回,磁性41被磁铁61移向右侧(图中所示情况下,磁铁77的磁力也起作用),头部42被止动件45接纳,在止动件45上完成向输送杆前端50的移送,然后,输送杆44被送进直至固定在其前端的磁性41接近孔63为止。此时输送杆44停止,与此几乎同时,锁紧件74被气缸72上移,从而控制销70也被同时上移,

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其位移通过内轴66、固定螺栓67和滑动件64传递到磁铁61。最后,使磁铁61和77与头部42间隔开来,因此作用在头部42上的磁力同时消失,螺栓以其前端首先落入孔63中。

现在描述图15和16所示的实施例。其中,暂时锁固在短管51中的螺栓41由一驱动装置88强制地移向输送杆44。在本实施例中,这种移送是由驱动气缸89和其活塞杆90实现的。从短管51分出一支管即导管91,驱动气缸89固定在导管91上,活塞杆90的前端如图16所示终止于一弧形凹口92。在本实施例中,夹持件53具有一四边形的横截面以改善其夹持头部42的能力。清楚前一实施例的工作过程后很容易理解本实施例的工作过程。因此这里省略了对夹持的描述。另外,本实施例的其它结构也与前一实施例相同。

在图17所示实施例中,输送管的端部,也就是短管51的端部装有一止动件93以便有力地阻止下行的螺栓41。夹持件53被设计成穿过短管上的一凹口94。

在图18和19所示的实施例中,输送杆装置是一个上螺母器79。上螺母器79由一转动轴80和一可与六方螺栓头部42配合的箱81构成。一嵌有磁铁82以便使螺栓41定位的载体83如图所示可由一气缸84送进和撤回。当上螺母器79下行直至箱81配合在头部42上时,载体83被撤回,螺栓41被送入一配合件(未画)的螺孔中。此时螺栓41被转动以拧紧。

图20所示实施例适用于螺栓41具有一弹簧垫圈85和一普通垫圈86的情况。一滑动件64上有一与普通垫圈86相适应的弧形凹口87。

按照本发明,通过了输送管的一细长零件一旦被输送管内表面和夹持件的配合动作所截住,细长零件即具有了向输送杆移送的正确姿态。因此,当夹持件的夹持作用取消时,细长零件开始移向其正常位置,从而移至输送杆装置的前端。

由于零件被磁铁固定于输送杆装置的前端,因而不会发生前述夹盘机构的问题。而且由于输送管是与输送杆装置行程的方向呈锐角设置的,前述导槽引起的安装空间的问题即可消除。

输送管倾斜地设置在输送杆装置的前端,因此,当细长零件移至输送杆装置的前端时,可以利用细长零件自身的重量,其方向和速度更符合需要。

由于利用磁铁的磁力移送零件,因而移送动作更为可靠迅速。

另外,由于磁铁装在上止动件的外侧,在输送杆

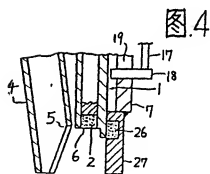
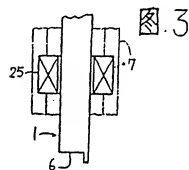
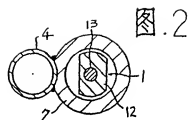
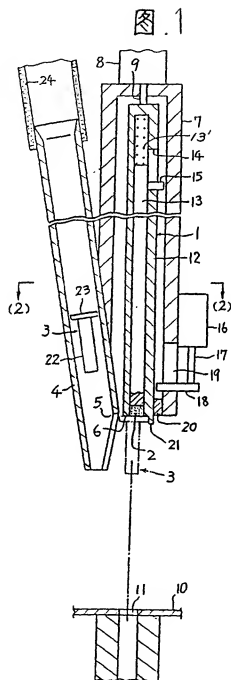
10

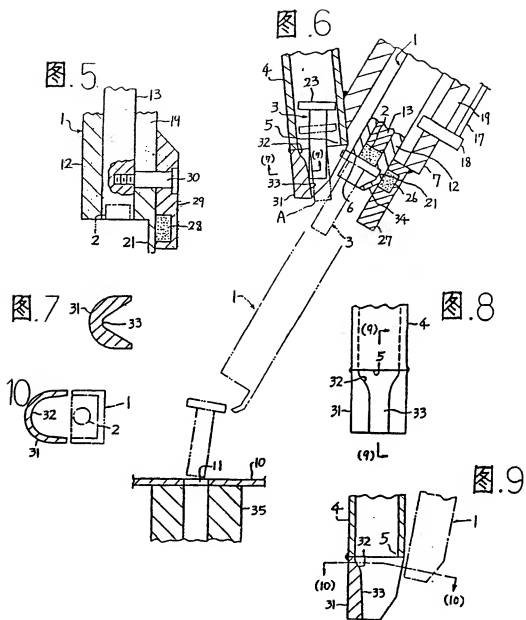
装置前端夹持零件的能力可得到进一步改善。

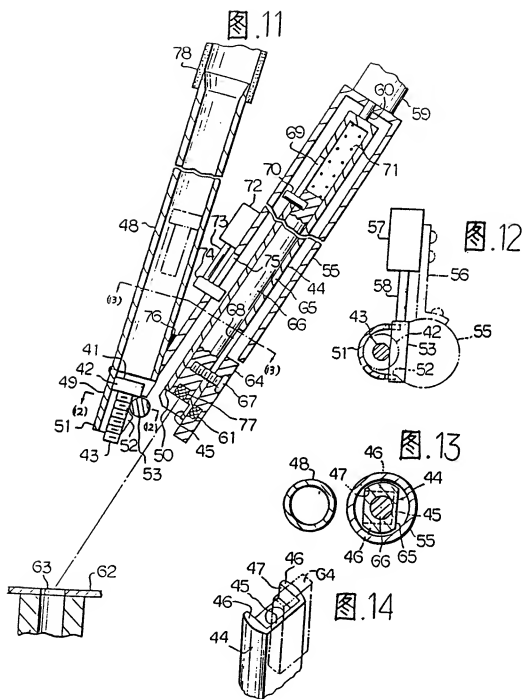
由于采用上螺母器作为输送杆装置,因而可精确方便地实现螺栓的自动拧紧。

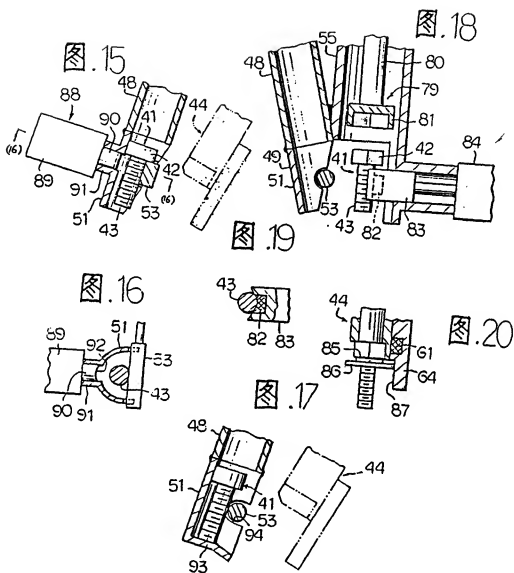
由于在与输送管配合工作的那一侧装有驱动装置,细长零件可被强制地移向输送杆,甚至当必须撑起细长零件的情况下,该驱动装置也可不出故障地完成其移送动作。

由于在输送管端部设有止动件,因而细长零件迅速下行时可以可靠地停住,而且工作也很可靠。











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- [JP 63104360 \(A\)](#)

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①7 Patentschrift
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Innerhalb von 3 Monaten nach Veröffentlichung der Erteilung kann Einspruch erhoben werden

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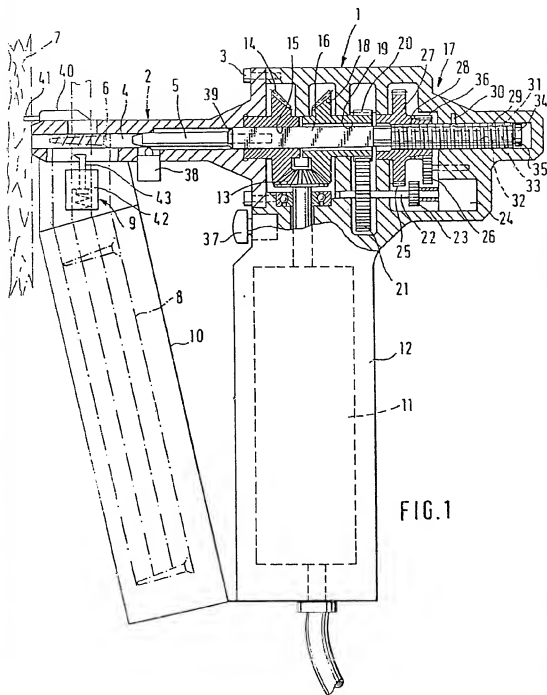
⑤5 Für die Beurteilung der Patentfähigkeit
in Betracht gezogene Druckschriften:

DE 28 28 379 A1
DE 28 07 677 A1
DE 26 41 828 A1
DE 22 10 789 A1
DE 17 03 418 A1

⑤6 Einschraubgerät

DE 33 33 427 C 2

DE 33 33 427 C 2



Beschreibung

Die Erfindung betrifft ein Einschraubgerät gemäß Oberbegriff von Anspruch 1 und 2.

Aus der DE-26 41 828 A1 ist ein Einschraubgerät der genannten Gattung bekannt, mit dem zu einem Schraubstreifen verbundene Schrauben einschraubbar sind, wobei diese Schrauben durch eine Zuführvorrichtung aus einem Magazin einem Führungsfuß zugeführt werden. Dieser Führungsfuß ist verschiebbar an einem mit einer Einschraubklinge versehenen Antriebsmotor angeordnet, wobei zum Einschrauben der Schraube der Antriebsmotor gegen den Führungsfuß von Hand gegen Federwirkung verschoben werden muß. Bei dieser Vorschubbewegung wird gleichzeitig die Zuführvorrichtung betätigt.

Aus der DE 17 03 418 A1 ist ein Einschraubgerät bekannt, bei dem der Antriebsmotor linear im Anschluß an die Einschraubklinge angeordnet ist. Das Einschraubgerät wird daher entsprechend verlängert und ist besonders bei beengten Raumverhältnissen schlecht zu handhaben. Der Vorschub der Einschraubklinge erfolgt pneumatisch, bei Verwendung eines Elektromotors zum Antrieb der Einschraubklinge ist daher zusätzlich zum elektrischen Anschluß noch eine Druckleitung notwendig. Damit wird dieses bekannte Einschraubgerät in weiterem Maße teuer und unhandlich.

Weiterhin zeigt die DE 22 10 789 A1 ein pneumatisches Kombinationswerkzeug zum Einschrauben und Kröpfen von Muttern, bei dem der Antriebsmotor quer zur Achse der Einschraub- und Kröpfvorrichtung angeordnet ist. Ein Hubkeil führt dabei eine Axialbewegung aus, die jedoch lediglich zum Umschalten von einer Einschraubstellung in eine Kröpfstellung führt.

Aus der DE 28 28 379 A1 ist noch ein Druckluftwerkzeug bekannt, dessen Absperrventil eine Führungsanordnung aufweist, die durch einen Elektromagneten fixierbar ist, d. h. dieser Elektromagnet dient zur Betätigung eines Ventils.

Der Erfindung liegt daher die Aufgabe zugrunde, ein Einschraubgerät der eingangs genannten Art zu schaffen, das bei kompakter Bauweise mit nur einer Hand bequem bedienbar ist und das eine hohe Arbeitsgeschwindigkeit erlaubt.

Diese Aufgabe wird erfindungsgemäß durch die im kennzeichnenden Teil der Ansprüche 1 und 2 angegebenen Merkmale gelöst.

Ein Einschraubgerät gemäß Erfindung ergibt eine kompakte und kurze Bauweise, dessen Griff in der Nähe des Schwerpunktes des Gesamtgerätes liegt und das verhältnismäßig leicht ausgeführt werden kann. Es ist somit zuverlässig mit einer Hand bedienbar, so daß die andere Hand des Bedienungsmanne frei ist zum Festhalten z. B. des anzuschraubenden Werkstückes. Da die Relativbewegung zwischen Antriebsmotor und Führungsfuß entfällt und der Vorschub und Rückhub der Einschraubklinge unabhängig von der Bewegung des Bedienungsmanne erfolgt, ergibt sich eine Steigerung der Arbeitsgeschwindigkeit.

Im folgenden sind Ausführungsbeispiele der Erfindung unter Bezugnahme auf die Zeichnungen näher beschrieben. Es zeigt

Fig. 1 Einschraubgerät mit elektrischem, quer zur Achse der Einschraubklinge angeordnetem Antriebsmotor, teilweise geschnitten,

Fig. 2 Einschraubgerät mit elektrischem, axial angeordnetem Antriebsmotor, teilweise geschnitten,

Fig. 3 Einschraubgerät mit einer weiteren Ausführungsform der Vorschubvorrichtung, teilweise geschnitten,

Fig. 4 Einschraubgerät mit druckluftbetriebenem, axial angeordnetem Antriebsmotor, teilweise geschnitten.

Bei dem in Fig. 1 dargestellten Einschraubgerät ist mit einem Gehäuse 1 ein Führungsfuß 2 durch Gehäuse-schrauben 3 fest verbunden. In einer Führungsbohrung 4 ist eine Einschraubklinge 5 axial verschiebbar gelagert, die zum Einschrauben einer bereitgestellten Schraube 6 in ein Werkstück 7 dient. Diese Schraube 6 ist Teil eines spiralförmig aufgewickelten Schraubestreifens 8, der der Führungsbohrung 4 durch eine Zuführvorrichtung 9 aus einem Magazin 10 zugeführt wird.

Zum Antrieb der Einschraubklinge 5 dient ein elektrischer Antriebsmotor 11, der quer zur Achse der Einschraubklinge 5 in einem Griffteil 12 von Gehäuse 1 angeordnet ist. Dieser Antrieb erfolgt über ein vom Antriebsmotor 11 antreibbares Kegelrad 13 auf ein axial zur Einschraubklinge 5 angeordnetes Kegelrad 14, das einen zentrischen Durchbruch 15 mit quadratischem Querschnitt aufweist. In diesem Durchbruch 15 ist Mitnehmereile 16 von Einschraubklinge 5, ebenfalls mit quadratischem Querschnitt, verschiebbar gelagert.

Die Vorschubvorrichtung 17 für die Einschraubklinge 5 weist ein weiteres Kegelrad 18 auf, das ebenfalls zentrisch zur Einschraubklinge 5 im Gehäuse 1 gelagert und vom Kegelrad 13 antreibbar ist. Seine zentrische Bohrung 19 weist jedoch einen größeren Durchmesser auf als der größte Querschnitt von Mitnehmereile 16.

Über ein mit dem Kegelrad 18 verbundenes Ritzel 20 ist ein Zahnrad 21 antreibbar, das mit einer Welle 22 fest verbunden ist, auf der ein Kupplungsrad 23 verschiebbar gelagert ist. Kupplungsrad 23 ist durch einen Elektromagneten 24 verschiebbar und kann wahlweise mit einem Zahnrad 25 oder Zahnrad 26 zusammenwirken. Zahnrad 25 ist Teil einer Antriebshülse 27, die eine zentrische Gewindebohrung 28 aufweist. Diese Gewindebohrung 28 wirkt mit einer Schraubspindel 29 zusammen, die im Gehäuse 1 axial verschiebbar gelagert ist. Um ein Drehen der Schraubspindel 29 zu verhindern, greift ein Stift 30 in eine Längsnut 31 der Schraubspindel 29 ein.

Die Schraubspindel 29 weist eine zentrische Bohrung 32 auf, durch die sich ein Zapfen 33 der Einschraubklinge 5 erstreckt. Am hinteren Ende von Zapfen 33 ist ein Bund 34 befestigt, der sich gegen die Stirnfläche 35 von Schraubspindel 29 legt.

Die Antriebshülse 27 weist ferner ein Ritzel 36 auf, mit dem das frei drehbar gelagerte Zahnrad 26 zusammenwirkt.

Der elektrische Teil des Einschraubgerätes weist ferner einen Schalter 37 für den Antriebsmotor 11 und einen Tastschalter 38 auf, mit dem eine Kontaktfeder 39 der Einschraubklinge 5 zusammenwirkt.

Ferner ist am vorderen Ende von Führungsfuß 2 ein Aufsatzraster 40 vorgesehen, dessen Taststift 41 beim Aufsetzen des Einschraubgerätes auf das Werkstück 7 betätigbar ist.

Zur Förderung von Schraubestreifen 8 ist die Zuführvorrichtung 9 mit einem Elektromagneten 42 versehen, mit dem ein mit dem Schraubestreifen 8 zusammenwirkender Zuführhänger 43 betätigbar ist.

Zum Betrieb des Einschraubgeräts wird Elektromotor 11 über Schalter 37 eingeschaltet. Das Kegelrad 13 versetzt dann die beiden Kegelräder 14 und 18 in Drehung, wobei der Durchbruch 15 mit quadratischem Querschnitt die Einschraubklinge 5 ebenfalls in Dre-

hung versetzt. Das zweite Kegelrad 18 treibt über Ritzel 20 und Zahnrad 21 zwar das Kupplungsrad 23 an, dieses befindet sich jedoch in einer Zwischenstellung, so daß die Vorschubhülse 27 stillsteht. Auch wird die Schraubspindel 29 durch Stift 30 an einer Drehung gehindert, obwohl sich der Zapfen 33 in der Bohrung 32 von Schraubspindel 29 dreht.

In der Führungsbohrung 4 ist eine Schraube 6 bereitgestellt, die in das Werkstück 7 eingeschraubt werden soll. Wird jetzt das Einschraubgerät auf das Werkstück 7 aufgesetzt, dann wird Taststift 41 eingedrückt und Aufsetztaster 40 betätigt, der seinerseits den Elektromagneten 24 der Vorschubvorrichtung 17 so einschaltet, daß sich Kupplungsrad 23 in Richtung von Zahnrad 25 bewegt und mit diesem zusammenwirkt. Damit beginnt sich die Vorschubhülse 27 zu drehen und sich die Schraubspindel 29 in Richtung Werkstück 7 zu verschieben. Damit wird auch Einschraubklinge 5 in Richtung Werkstück 7 verschoben und Schraube 6 in dieses eingeschraubt, bis z. B. der Kopf bündig ist mit der Oberfläche von Werkstück 7. In diesem Augenblick betätigt Kontaktfläche 39 von Einschraubklinge 5 den Tastschalter 38, der zum einen den Elektromagneten 24 umschaltet und zum anderen den Elektromagneten 42 der Zuführvorrichtung 9 betätigt.

Der umgeschaltete Elektromagnet 24 bewegt das Kupplungsrad 23 in Richtung Zwischenrad 26, das damit nach Eingriff mit Kupplungsrad 23 angetrieben wird und die Vorschubhülse 27 über Ritzel 36 in umgekehrter Richtung dreht, so daß die Einschraubklinge 5 über Schraubspindel 29 in ihre Ruhestellung zurückgezogen wird. Diese Rückhubbewegung kann durch einen nicht dargestellten Endschalter beendet werden, wobei Elektromagnet 24 das Kupplungsrad 23 wieder in seine Zwischenstellung befördert.

Beim Aufsetzen des Einschraubgeräts auf das Werkstück 7 wurde der Elektromagnet 42 der Zuführvorrichtung 9 durch den Aufsetztaster 40 so betätigt, daß sich der Zuführfinger 43 gegen Federwirkung von der Führungsbohrung 4 wegbewegt. Nachdem die Einschraubklinge 5 nach dem Rückhub wieder ihre Endstellung erreicht hat, kann der bereits erwähnte Endschalter den Elektromagneten 42 ausschalten, so daß der Zuführfinger 43 die nächste Schraube des Schraubenstreifens 8 in die Führungsbohrung 4 einschleibt. Das Gerät ist damit wieder bereit für den nächsten Einschraubvorgang.

Bei einem weiteren Ausführungsbeispiel der Erfindung gemäß Fig. 2 ist der elektrische Antriebsmotor 44 konzentrisch zur Achse der Einschraubklinge 5 in einem Gehäuse 45 gelagert. Der Führungsfuß 2, das Magazin 50 und die Vorschubvorrichtung 17 entsprechen im übrigen dem Ausführungsbeispiel gemäß Fig. 1.

Beim Ausführungsbeispiel gemäß Fig. 2 weist der Anker 46 von Antriebsmotor 44 eine zentrische Bohrung 47 auf, durch die sich die Einschraubklinge 5 erstreckt. Der Antrieb dieser Einschraubklinge 5 erfolgt über ein mit dem Anker 46 verbundenes Ritzel 48, das über Zwischenräder 49 und 50 das Mitnehmerrad 51 antreibt. Dieses versetzt die Einschraubklinge 5 wieder über deren Mitnehmerstück 16 mit quadratischem Querschnitt in Drehung.

Über ein zweites Ritzel 52, das ebenfalls mit dem Anker 46 verbunden ist, wird die Vorschubvorrichtung 17 in der beschriebenen Weise angetrieben.

Die Funktion des Ausführungsbeispiels gemäß Fig. 2 entspricht der Funktion des Ausführungsbeispiels gemäß Fig. 1.

Wie Fig. 3 zeigt, kann für die Vorschub- und Rück-

hubbewegung der Einschraubklinge 5 anstelle eines Getriebes, wie in Fig. 1 und 2 dargestellt, auch eine Vorschubvorrichtung 53 mit einem Elektromagneten 54 vorgesehen sein. In einer zentrischen Bohrung 55 dieses Elektromagneten 54 bewegt sich ein Eisenkern 56, durch dessen zentrische Bohrung 57 sich der Zapfen 33 der Einschraubklinge 5 erstreckt. Der Elektromagnet 54 kann wieder durch den Aufsetztaster 40 so betätigt werden, daß er die Einschraubklinge 5 gegen Wirkung einer nicht dargestellten Feder in Richtung Werkstück 7 bewegt. Nach Ausschalten des Elektromagneten führt die nicht dargestellte Feder die Einschraubklinge 5 wieder in ihre rückwärtige Ruhestellung.

Bei einem weiteren Ausführungsbeispiel der Erfindung gemäß Fig. 4 erfolgt der Antrieb der Einschraubklinge 5 über einen druckluftbetriebenen Antriebsmotor 58, der durch ein Schaltventil 59 ein- und ausschaltbar ist. Die Lagerhülse 60 weist wiederum, wie beim Ausführungsbeispiel gemäß Fig. 2, eine zentrale Bohrung 61 auf, in der die Einschraubklinge 5 axial verschiebbar angeordnet ist. An ihrem vorderen Teil ist die Lagerhülse 60 mit einem Mitnehmerabschnitt 62 mit quadratischem Querschnitt versehen, der mit dem Mitnehmerstück 16 der Einschraubklinge 5 ebenfalls mit quadratischem Querschnitt zusammenwirkt.

Als Vorschubvorrichtung 63 für die Einschraubklinge 5 dient ein druckluftbetriebener Vorschubkolben 64, der in einem mit dem Gehäuse 65 verbundenen Einschiebzyylinder 66 gegen Wirkung einer Druckfeder 67 verschiebbar gelagert ist. Er weist eine Hülse 68 auf, durch deren Bohrung 69 sich der Zapfen 33 der Einschraubklinge 5 erstreckt. Der Tastschalter 70 und der Aufsetztaster 71 sowie die Zuführvorrichtung 72 sind bei diesem Ausführungsbeispiel natürlich als Druckluftventile bzw. -kolben ausgeführt.

Der Betrieb dieses mit Druckluft betriebenen Einschraubgeräts erfolgt wieder analog, wie bereits bei den vorhergehenden Ausführungsbeispielen beschrieben. Der Vorschubkolben 64 wird jedoch so vom Aufsetztaster 71 gesteuert, daß der Vorschubzylinder 66 beim Eindringen von Taststift 41 mit Druckluft beaufschlagt wird und den Vorschubkolben 64 und damit die Einschraubklinge 5 in Richtung Werkstück 7 verschiebt. Nach Beendigung des Einschraubvorgangs und Rückkehr der Einschraubklinge 5 in ihre Ruhestellung kann Vorschubzylinder 66 so entlüftet werden, daß Vorschubkolben 64 und damit auch Einschraubklinge 5 unter Wirkung der Druckfeder 67 in die Ruhestellung zurückkehren.

Die Zuführvorrichtung 72 besteht hier aus einem Zuführkolben 73, der in einem Zuführzylinder gegen Federwirkung verschiebbar gelagert ist. Zuführkolben 73 läßt sich ebenso, wie bereits oben beschrieben, über Aufsetztaster 71 steuern.

Patentansprüche

1. Einschraubgerät mit einem Gehäuse zur Aufnahme eines Antriebsmotors, einem mit dem Gehäuse fest verbundenen Führungsfuß, einer im Führungsfuß drehbar und verschiebbar gelagerten Einschraubklinge und einer am Führungsfuß angeordneten Zuführvorrichtung für die Schrauben, dadurch gekennzeichnet, daß die Einschraubklinge (5) verschiebbar in einer zentrischen Bohrung (47, 61) des Antriebsmotors (44, 58) gelagert ist.
2. Einschraubgerät mit einem Gehäuse zur Aufnahme eines Antriebsmotors, einem mit dem Gehäuse

fest verbundenen Führungsfuß, einer im Führungs-
fuß drehbar und verschiebbar gelagerten Ein-
schraubklinge und einer am Führungsfuß angeord-
neten Zuführvorrichtung für die Schrauben, da-
durch gekennzeichnet, daß der quer zur Achse der
Einschraubklinge (5) angeordnete Antriebsmotor
(11) mit einem Winkelgetriebe (13, 14) gekuppelt
ist, dessen eines Kegelrad (14) einen Durchbruch
(15) aufweist, in dem die Einschraubklinge (5) ver-
schiebbar gelagert ist.

3. Einschraubgerät nach Anspruch 1 oder 2, da-
durch gekennzeichnet, daß zum axialen Verschie-
ben der Einschraubklinge (5) eine Vorschubvor-
richtung (17) vorgesehen ist, bei der eine mit der
Einschraubklinge (5) kraftschlüssig verbundene
Schraubspindel (29) mit der vom Antriebsmotor
(11) antreibbaren Vorschubhülse (27) zusammen-
wirkt.

4. Einschraubgerät nach Anspruch 1 oder 2, da-
durch gekennzeichnet, daß zum axialen Verschie-
ben der Einschraubklinge (5) eine Vorschubvor-
richtung (63) vorgesehen ist, die einen druckluftbe-
triebenen Vorschubkolben (64) aufweist.

5. Einschraubgerät nach Anspruch 1 oder 2, da-
durch gekennzeichnet, daß zum axialen Verschie-
ben der Einschraubklinge (5) eine Vorschubvor-
richtung (53) vorgesehen ist, die einen Elektroma-
agneten (54) aufweist.

6. Einschraubgerät nach einem der Ansprüche 1 bis
5 mit einem an sich bekannten Aufsetztaster, da-
durch gekennzeichnet, daß die Vorschubvorrich-
tung (17, 53, 63) durch den Aufsetztaster (40, 71)
betätigbar ist.

7. Einschraubgerät nach einem der Ansprüche 1 bis
6, dadurch gekennzeichnet, daß ein Tastschalter
(38, 70) vorgesehen ist, mit dem ein mit der Ein-
schraubklinge (5) verbundenes Auslöseorgan (39)
zur Betätigung einer Zuführung (9, 72) zusammen-
wirkt.

8. Einschraubgerät nach Anspruch 7, dadurch ge-
ennzeichnet, daß ein die Zuführvorrichtung (9) be-
tätigbarer Elektromagnet (42) vorgesehen ist.

9. Einschraubgerät nach Anspruch 7, dadurch ge-
ennzeichnet, daß ein die Zuführvorrichtung (72)
betätigbarer, druckluftbetriebener Zuführkolben
(73) vorgesehen ist.

Hierzu 3 Seite(n) Zeichnungen

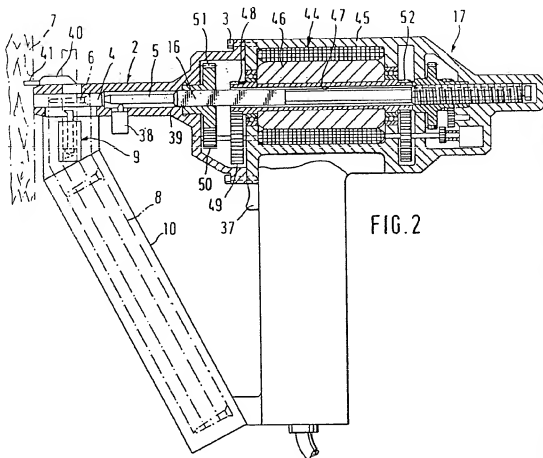


FIG. 2

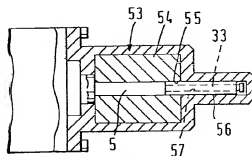
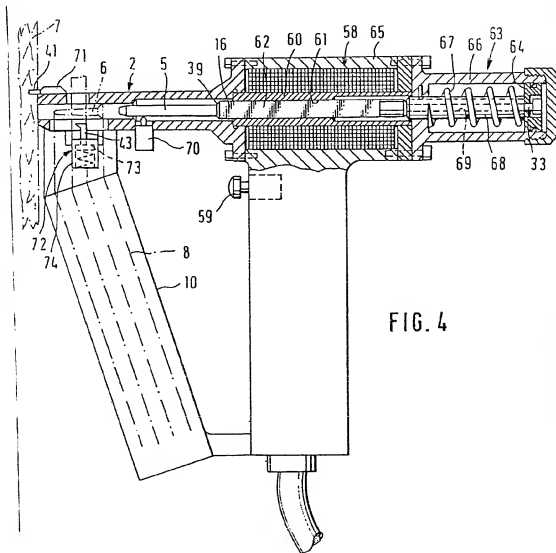


FIG. 3





Espacenet

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TUBULAR SURGICAL IMPLANT

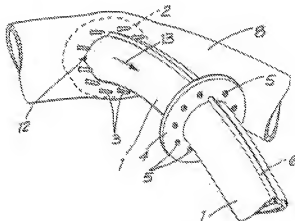
Publication date: 1999-09-16
Inventor(s): OWEN EARL [AU] ±
Applicant(s): OWEN EARL [AU] ±
Classification:
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- WO 9300868 (A1)
- US 5458714 (A)
- JP 750023 (T)
- EP 0593600 (A1)
- EP 0543600 (B1)
- EP 0543600 (B1)

Abstract not available for DE 69228184 (T2) Abstract of corresponding document: WO 9300868 (A1)

A tubular surgical implant particularly suitable for use in heart bypass surgery comprising a tube (1) having a flange (2) adapted to be folded and inserted into a cut in a vessel (5). The flange has a series of spikes (3) parallel to the tube which pass through the vessel wall and are engaged with holes (6) in a locking ring (4) slidable on the tube (1). The implant is typically connected between an aorta and a distal coronary artery in a heart bypass operation.



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17 Übersetzung der
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NL, SE

21 Erfinder:
gleich Anmelder

50 ROHRFÖRMIGES, CHIRURGISCHES IMPLANTAT

Anmerkung: Innerhalb von neun Monaten nach der Bekanntmachung des Hinweises auf die Erteilung des europäischen Patents kann jedermann beim Europäischen Patentamt gegen das erteilte europäische Patent Einspruch einlegen. Der Einspruch ist schriftlich einzureichen und zu begründen. Er gilt erst als eingelegt, wenn die Einspruchsgebühr entrichtet worden ist (Art. 99 (1) Europäisches Patentübereinkommen).

Die Übersetzung ist gemäß Artikel II § 3 Abs. 1 IntPatÜG 1991 vom Patentinhaber eingereicht worden. Sie wurde vom Deutschen Patent- und Markenamt inhaltlich nicht geprüft.

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Schlauchförmiges chirurgisches ImplantatTechnischer Bereich

Die Erfindung bezieht sich auf ein schlauchförmiges chirurgisches Implantat und ist insbesondere, obwohl nicht ausschließlich, für den Einsatz als Bypass und insbesondere als Koronar-Bypasseinrichtung entwickelt worden.

Stand der Technik

Die sogenannte "Herz-Bypass-Chirurgie" ist relativ üblich und wird notwendig bei einer Blockade oder einer teilweise Blockade, die durch eine Verengung der Koronararterien entsteht und die zu Ischaemia oder - distal - zu einem Ausbleiben der Blutversorgung des Herzmuskels führt. Der als Folge davon gefühlte Schmerz ist als Angina bekannt und die Folge kann eine Herzattacke, Tod oder Wiedergenesung mit einer Beschädigung des Herzmuskels sein. Die gegenwärtige Behandlungsmethode durch die Herz-Bypass-Chirurgie ist effektiv, aber aufwendig in der Ausführung, zeitaufwendig und erfordert den Stillstand des Herzens und die Anordnung des Patienten in einer lebenserhaltenden künstlichen Herz-Lungen-Maschine unter Einsatz großer Mengen von Blut. Die Chirurgen müssen dann Beinvenen oder Brustarterien oder beides abnehmen, um sie als Bypass von der Aorta zu der distalen Koronararterie zu positionieren und zu vernähen.

Es ist wünschenswert, ein wesentlich weniger kompliziertes Verfahren zur Ausführung einer Bypassoperation vorzusehen, das nicht nur schneller und weniger aufwendig in der Durch-

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führung ist, sondern auch wesentlich weniger Risiko für den Patienten zur Folge hat.

Die DE-A-26 57 255 offenbart ein schlauchförmiges chirurgisches Implantat, das dazu geeignet ist, mit der Wand eines Gefäßes (d.h. eines Blutgefäßes) verbunden zu werden. Das Implantat besitzt an einem Ende des Schlauches einen Flansch, aber dieser Flansch ist nicht flexibel und wird im Gebrauch daher an der Außenseite des Gefäßes angeordnet. Die Befestigung des Implantates am Gefäß macht es daher notwendig, einen etwas komplexen chirurgischen Eingriff vorzunehmen, der die Anordnung eines Tragringes innerhalb des Gefäßes beinhaltet, an dem dann der Flansch befestigt werden kann.

Die WO 82/01644 offenbart ein anastomotisches Anschlußstück zum Einsetzen in ein Gefäß. In diesem Fall ist ein fester distaler Flansch innerhalb des Gefäßes angeordnet, der durch eine dann notwendig werdende chirurgische Einfügung angebracht wird, d.h. die einen ausreichend großen Schnitt zum Einsetzen des Flansches notwendig macht. Auch hier besteht die Befestigung des Implantates am Gefäß aus einem komplexen chirurgischen Verfahren, bei dem ein frei beweglicher Befestigungsring gegen den innerhalb des Gefäßes sitzenden Flansch gedrückt wird. Der Befestigungsring wird dann in seiner Lage durch einen weiteren Verschlußring gehalten.

Offenbarung der Erfindung

Die vorliegende Erfindung sieht ein schlauchförmiges chirurgisches Implantat vor, das mit einer Wand eines Gefäßes 8 oder eines Hohlorgans so verbunden werden kann, daß sich das Implantat in das Innere des Gefäßes oder Organs öffnet, wobei das Implantat einen Schlauch 1 mit einem offenen Ende und mit einem Flansch 2 an einem Ende des Schlauches umfaßt, der mit einer Vielzahl von Dornen 3 versehen ist, die von ihm abstehen, und zwar längs und im wesentlichen parallel zu dem

Schlauch, sowie aus einem Klemmring 4, der eine Vielzahl von Löchern 5 aufweist, die zu den Dornen ausgerichtet sind und diese aufnehmen können, und das dadurch gekennzeichnet ist, daß der Flansch im Verhältnis zum Schlauch verformbar ist, so daß er zur Einführung in eine Öffnung 12 in der Gefäßwand oder der Wand des Organs am Schlauch anliegt, und daß der Klemmring so angeordnet ist, daß er in Längsrichtung auf dem Schlauch verschoben werden kann.

Vorzugsweise ist der Klemmring am Schlauch über eine Art Paßfederanordnung gesichert, um die Drehung des Rings relativ zum Schlauch zu verhindern. Vorzugsweise sind die Dornen und die Löcher im Klemmring mit einem Verriegelungsmechanismus versehen, der dazu dient, die Dornen in den Löchern zu halten, wenn sich der Klemmring mit den Dornen in Eingriff befindet.

Alternativ kann der Flansch quer zu einer oder mehreren Gelenklinien im Flansch deformierbar sein, damit Teile des Flansches zur Einführung in die Öffnung in der Wand des Gefäßes oder Organs gegen den Schlauch zurückgebogen werden können. In einer Ausführungsform der Erfindung ist das Implantat dazu geeignet, zwei Gefäße oder Hohlorgane zu verbinden, und ist zu diesem Zweck an beiden Enden des Schlauchs mit einem Flansch und einem Klemmring versehen.

Vorzugsweise kann der Schlauch und der Flansch aus einem Maschenmaterial aus Kunststoff hergestellt werden, das die Einbeziehung von menschlichem Gewebe erlaubt.

Kurzbeschreibung der Zeichnungen

Eine bevorzugte Ausführungsform der Erfindung ist beispielhaft anhand der beigefügten Zeichnungen beschrieben, wobei dies nicht bedeutet, daß nicht auch andere Ausführungsformen mit unter deren Umfang fallen. In den Zeichnungen zeigen:

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- Fig. 1 eine schematische Ansicht eines schlauchförmigen chirurgischen Implantats nach der Erfindung,
- Fig. 2 eine Teilansicht eines Endes des Implantats der Fig. 1,
- Fig. 3 eine schematische Ansicht eines Blutgefäßes, das abgeklemmt und mit einem Präparationsschnitt zur Verbindung mit dem schlauchförmigen chirurgischen Implantat der Fig. 1 versehen ist,
- Fig. 4 eine schematische perspektivische Ansicht des Implantates während des Einsetzens in den Einschnitt des Gefäßes,
- Fig. 5 eine Ansicht ähnlich Fig. 4, die zeigt, wie die Dornen des Implantats in Eingriff gebracht werden und
- Fig. 6 eine Ansicht ähnlich zu den Figuren 4 und 5, die aber den Eingriff des Klemmringes zeigen.

Ausführungsformen für die Erfindung

In der bevorzugten Ausführungsform der Erfindung ist ein schlauchförmiges chirurgisches Implantat für den Einsatz als Bypass zwischen der Aorta und einer Koronararterie vorgesehen, obwohl es durchaus auch möglich ist, daß die Vorrichtung bei vielen anderen Anwendungen eingesetzt wird, immer dann, wenn es notwendig wird, einen künstlichen Schlauch mit einem Gefäß oder Organ zu verbinden, oder einen Bypass zwischen verschiedenen Gefäßen und/oder Organen herzustellen. Das Implantat wird anhand einer Doppelendenvorrichtung beschrieben,

obwohl es auch möglich ist, daß bei manchen Anwendungen Befestigungsflansch und Klemmring nur an einem Ende des Schlauches vorgesehen werden.

Das Implantat besteht aus einem Schlauch 1 mit einem Flansch 2 an beiden Enden des Schlauches. Der Schlauch und der Flansch können aus jedem geeigneten Material hergestellt werden, werden aber insbesondere aus einem Maschenmaterial aus Kunststoff, wie beispielsweise aus einer bestimmten Klasse von Goretex (eingetragene Marke) hergestellt, welches den Einschluß eines menschlichen Gewebes und eine lange Lebensdauer der Vorrichtung im Körper ermöglicht.

Jeder Flansch ist mit einer Vielzahl von Dornen 3 versehen, die vom Flansch aus längs und im wesentlichen parallel zum Schlauch abstehen. Die Dornen stehen dabei in einer Richtung vom offenen Ende des Schlauches ab, die vom offenen Ende wegweist.

Das Implantat ist außerdem mit Klemmringen 4 versehen, die im wesentlichen die gleichen Abmessungen und Ausbildungen wie die Flansche 2 haben und axial verschiebbar auf dem Schlauch 1 angeordnet sind. Jeder Klemmring weist eine Mehrzahl von Löchern 5 (Fig. 5) auf, die zu den Dornen 3 ausgerichtet und geeignet sind, diese vom zugeordneten Flansch 2 abragenden Dornen aufzunehmen.

Um die Ausrichtung der Löcher 5 mit den Dornen 3 sicherzustellen, kann der Klemmring mit Hilfe einer Keilnut 6 auf dem Schlauch unverdrehbar gehalten sein, wobei eine entsprechende Aussparung oder Öffnung (nicht gezeigt) im Klemmring 4 die Verdrehung des Ringes zum Schlauch verhindert. Auf diese Weise können die Löcher 5 ganz genau zu den Dornen 3 ausgerichtet werden, so daß der Ring mit den Dornen in Eingriff gebracht werden kann, wie weiter unten noch beschrieben werden wird.

Der Flansch 2 ist relativ zum Schlauch 1 verformbar und zwar entweder dadurch, daß der gesamte Flansch relativ zum Schlauch verformt wird, so daß der Flansch am Schlauch zum Einsetzen in eine Öffnung eines Gefäßes oder Organs anliegt oder er kann alternativ auch längs einer oder mehrerer Gelenklinien 7 (Fig. 2) verformt werden, durch die Teile des Flansches gegen den Schlauch zurückgebogen werden können, wie das in der Fig. 4 für das Einsetzen in eine Öffnung in der Wand des Gefäßes oder Organs erforderlich ist.

Die Verwendung des Implantats wird nun unter Bezugnahme auf eine übliche Koronar-Bypassoperation beschrieben werden, wo das Implantat zwischen der Aorta und der distalen Koronararterie befestigt wird.

Nach der Fig. 3 wird zunächst die Aorta 8 teilweise mit Hilfe einer nichttraumatischen Klemme 9 abgeklemmt, die teilweise über die Aorta gelegt wird, um den weiteren Blutfluß durch den ungeklemmten Teil 10 zu erlauben. Der geklemmte Teil 11 der Aorta 8 wird dann aufgeschnitten, um einen Einschnitt 12 zur Aufnahme des Implantats zu bilden.

Wie in der Fig. 4 gezeigt ist, kann der Flansch 2 wie vorher beschrieben verformt und durch den Einschnitt 12 eingesetzt werden, bis der gesamte Flansch innerhalb der Aorta angeordnet ist. Der Flansch kann sich dann hinter der Gewebewand der Aorta zu seiner ursprünglichen Form öffnen oder er wird dazu veranlaßt, und der Schlauch wird in der Richtung des Pfeiles 13 (Fig. 5) zurückgezogen, so daß die Dornen 3 durch die Gewebewand 11 dringen.

Der Klemmring 4 wird dann längs des Schlauches verschoben, bis die Dornen 3 innerhalb der Löcher 5 im Klemmring aufgenommen werden, wie das in Fig. 6 gezeigt ist.

Die Dornen 3 und die Löcher 5 im Klemmring 4 sind mit einer Anzahl von Klemm-Mechanismen versehen, um die Dornen innerhalb der Öffnungen zu halten, wenn der Klemmring mit den Dornen nach Fig. 6 in Verbindung gebracht ist. Diese Verriegelungsbildung kann in jeder bekannten Ausbildung erfolgen, aber sie wird üblicherweise als eine Reihe von "Einrast"-Mechanismen ausgebildet, die den Klemmring in verschiedenen Abständen vom Flansch aufnehmen, um den Einsatz für verschiedene Aorta-Wandstärken zu ermöglichen.

Das Verfahren kann dann am anderen Ende des Implantats wiederholt werden, um die Verbindung des anderen Flansches mit der Koronararterie herzustellen, um so effektiv und schnell einen Bypass zwischen Aorta und Koronararterie vorzusehen.

Bei der speziellen Anwendung einer Herz-Bypassoperation kann der Flansch, der mit der Koronararterie verbunden werden soll, kleiner als der Flansch ausgebildet sein, der mit der Aorta verbunden wird, um eine gewisse Anpassung an die Abmessung des Gefäßes zu erreichen, an dem er angebracht werden soll. Dabei kann eine Reihe von verschieden bemessenen und unterschiedlich endenden Vorrichtungen verwendet werden, um die zu erwartenden Größen verschiedener Durchmesser und Wanddicken von Aorta und Koronararterien abzudecken. In den Fällen, in denen mehr als eine Blockade in der Koronararterie vorliegt, kann das schlauchförmige chirurgische Implantat auch als ein Anschlußstück mit einem größeren proximalen Aortaende und verschiedenen einzelnen distalen Koronarenden ausgebildet sein. Die Schläuche können dabei entweder mit parallelen Seitenwänden oder mit sich verengenden (konischen) Wänden versehen werden, je nach dem, wie das für die gewünschten Strömungsverhältnisse erforderlich ist.

Auf diese Weise wird ein chirurgisches Instrument zur Verfüugung gestellt, das eine Koronar-Bypassoperation ohne Anhalten der Herzfunktion oder der Aortablutströmung in den Körper er-

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möglichst, und welches außerdem das Abtrennen von Venen oder Arterien von anderen Körperteilen umgeht, die als Bypass-Leitungen verwendet werden sollen.

Das Implantat kann auch in vielen anderen Bereichen des Gebietes der Gefäß- oder Mikrochirurgie verwendet werden und kann überall dann eingesetzt werden, wenn es notwendig ist, einen Schlauch mit einem Gefäß oder Hohlorgan zu verbinden oder eine Verbindung zwischen zwei Gefäßen und/oder Organen herzustellen.

PATENTANSPRÜCHE

1. Schlauchförmiges chirurgisches Implantat, das mit einer Wand eines Gefäßes (8) oder Hohlorgans verbunden werden kann, derartig, daß sich das
- 5 Implantat in das Innere des Gefäßes oder Organs öffnet, wobei das Implantat folgende Komponenten umfaßt: einen Schlauch (1) mit offenem Ende, einen Flansch (2) an einem Ende des Schlauchs, der eine Vielzahl von Dornen (3) hat, die von diesem ausgehen und längs und allgemein parallel zu dem Schlauch verlaufen, und einen Klemmring (4), der eine Vielzahl von Löchern
- 10 (5) aufweist, die mit den Dornen ausgerichtet werden und diese aufnehmen können, dadurch gekennzeichnet, daß der Flansch im Verhältnis zum Schlauch verformbar ist, so daß der Flansch so verformt werden kann, daß er zur Einführung in eine Öffnung (12) in der Wand des Gefäßes oder Organs am Schlauch anliegt, und daß der Klemmring (4) so angeordnet ist, daß er in
- 15 Längsrichtung auf dem Schlauch verschoben werden kann.
2. Schlauchförmiges chirurgisches Implantat nach Anspruch 1, bei dem der Klemmring am Schlauch verkeilt (6) ist, um die Drehung des Rings im Verhältnis zum Schlauch zu verhindern.
3. Schlauchförmiges chirurgisches Implantat nach Anspruch 1 oder
- 20 Anspruch 2, bei dem die Dornen und die Löcher im Klemmring mit einem Verriegelungsmechanismus versehen sind, der so angeordnet ist, daß die Dornen in den Löchern gehalten werden, wenn sich der Klemmring mit den Dornen im Eingriff befindet.
4. Schlauchförmiges chirurgisches Implantat nach einem der
- 25 vorhergehenden Ansprüche, bei dem der Flansch quer zu einer oder mehreren Gelenklinien (7) im Flansch verformt werden kann, damit Teile des Flanschs zur Einführung in die Öffnung in der Wand des Gefäßes oder Organs gegen den Schlauch zurückgebogen werden können.
5. Schlauchförmiges chirurgisches Implantat nach einem der
- 30 vorhergehenden Ansprüche, bei dem das Implantat dafür geeignet ist, zwei Gefäße oder Hohlorgane zu verbinden, und an beiden Enden des Schlauchs mit einem Flansch und einem Klemmring versehen ist.
6. Schlauchförmiges chirurgisches Implantat nach einem der
- 35 vorhergehenden Ansprüche, bei dem der Schlauch und der Flansch aus einem Maschenmaterial aus Plastik hergestellt werden, das die Einbeziehung von menschlichem Gewebe erlaubt.

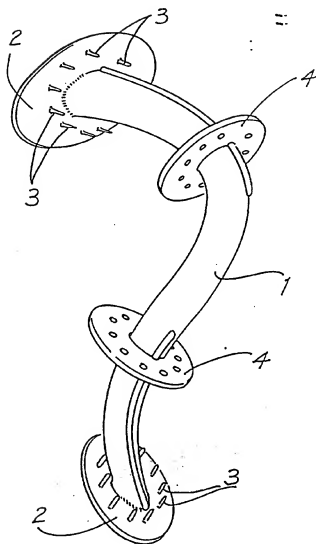
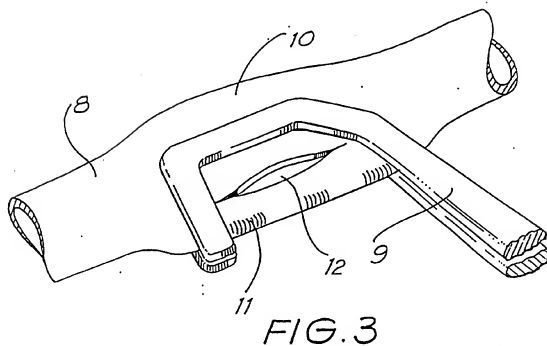
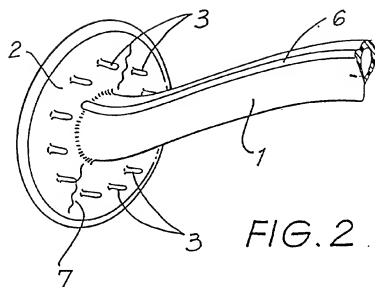


FIG. 1



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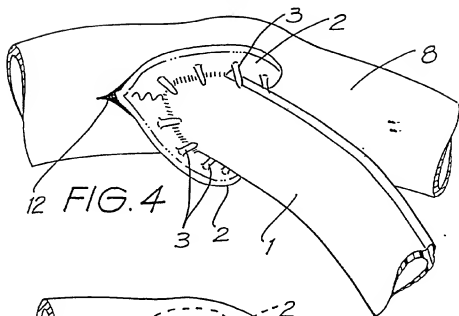


FIG. 4

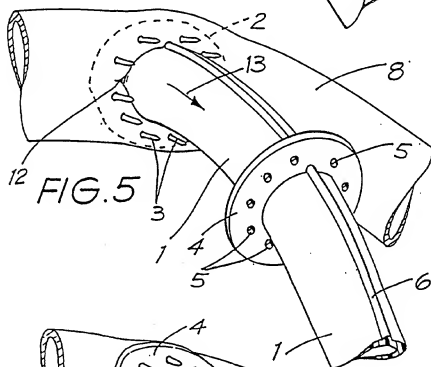


FIG. 5

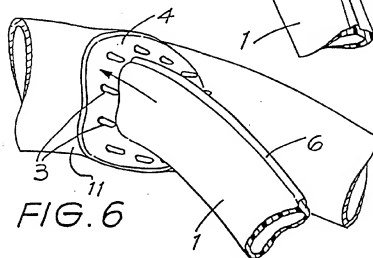


FIG. 6

(10)



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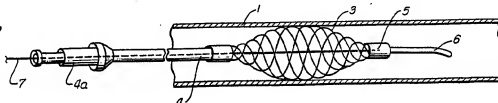
(54) Removable endo-arterial devices intended to repair detachments in arterial walls.

(57) The invention covers removable endo-arterial devices intended to repair detachments in the arterial walls.

A device according to said invention includes a deformable cuff (3) made of a netting of interlocked wires and fixed to the distal end of a catheter (4) the other end of which is equipped with a funnel (4a). It also includes a stiff wire (7) extending over the entire length of the catheter and attached to the distal end of said deformable cuff (3). When this wire is pulled, the cuff is dilated and applies itself against the arterial wall.

One application is the repair of flaps of arterial wall which were detached during the course of an intervention correcting a stenosis with an inflatable balloon.

Fig. 2



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REMOVABLE ENDO-ARTERIAL DEVICES INTENDED TO REPAIR DETACHMENTS IN ARTERIAL WALLS

Technical Field

The present invention provides endo-arterial devices temporarily installed in an artery in order to re-attach flaps which have been detached from the wall.

The technical field of the invention is the construction of surgical equipment used in cardio-vascular interventions.

Background of the Invention

There are known devices consisting of a small inflatable balloon at the end of a catheter used to dilate strictures in the arteries, especially the coronary arteries.

Such a catheter bearing a balloon is introduced into an artery, for example into the femoral artery, until the balloon reaches the stricture. The balloon is then inflated with a fluid pumped in through the catheter and pushes back the arterial wall, thus eliminating the stricture. The balloon must then be deflated very quickly, since it blocks the artery and impairs blood circulation.

It so happens that a similar intervention may cause detachments of the part of the arterial wall called intima, and the detached wall flaps inhibit the blood circulation and may result in severe medical complications and even be fatal if circulation is interrupted.

Devices consisting of a cylindrical elastic cuff inserted over an inflatable balloon fixed to the end of a catheter have been tried for the prevention of such accidents. The balloon is folded back over the cuff so as to keep the latter in an elongated shape of small diameter while it is being pushed through the arteries. Once the balloon bearing the elastic cuff has arrived at the site of the wall detachment, it is inflated so that the folded part slips loose releasing the cuff which increases in diameter and plasters itself against the internal wall of the artery where it remains indefinitely. This device not only has the inconvenience of introducing a foreign body into the artery to remain stationary there, but also presents risks of blood clots to the patient.

Brief Summary of the Invention

The present invention provides a device consisting of a deformable cuff made up of a net of twisted and interlocking wires mounted at the end of a catheter which is then introduced into an

artery. It also includes means activated from the external end of the catheter to move the two ends of the deformable cuff closer together or farther apart in order to give the cuff a wider shape which presses it against the arterial wall or a flat, elongated shape which permits introduction of the cuff and catheter into the artery or their withdrawal.

According to a preferred embodiment of the invention, the means used to reduce or extend the distance between the two ends of the deformable cuff are made up by a wire of the piano wire type which makes it possible to exert a push and which is fixed to the distal end of the cuff while freely passing through the proximal end of it and extending through the entire length of the catheter.

According to another embodiment, a device according to the present invention includes, in addition, an inflatable balloon located inside the deformable cuff and is mounted at the end of an inflation tube which, in turn, runs inside the catheter.

The invention provides new devices usable in cardio-vascular interventions, especially in interventions intended to remove stenoses of the coronary arteries in case of a severe risk of infarct or after an infarct has occurred.

Devices according to the present invention have the advantage that the deformable net allows the blood to pass between its mesh openings when it is applied against the wall of an artery. It can therefore be left in place for a duration on the order of one or more hours, which is more than sufficient to ensure cicatrization of the flaps detached from the arterial wall.

As compared to the known devices which involve an elastic cuff remaining stationary in the artery, devices according to the present invention have the advantage of being removable so that there is no risk of rejection phenomena or of the formation of blood clots. The devices according to the present invention include an inflatable balloon placed inside a cuff or deformable net, making it possible to treat a stenosis and, if necessary, to immediately repair the arterial wall. They therefore reduce the risk of postoperative complications and can even be used for interventions on strictures of the common trunk of the coronary arteries.

Description of the Drawings

The following detailed description refers to the enclosed drawings which represent examples of embodiments of the devices according to the present invention without being in any way limitative.

Fig. 1 is a longitudinal section of a first embodiment of a device according to this invention, in an elongated position.

Fig. 2 is a longitudinal section of a device according to Fig. 1 in the deployed position.

Fig. 3 is a longitudinal section of the fixation of the proximal end of the deformable cuff over the distal end of a catheter.

Fig. 4 is a longitudinal section of a second embodiment of a device according to this invention.

Fig. 5 is a longitudinal section of a third embodiment of a device according to this invention.

Fig. 6 is a cross section along VI-VI in Fig. 5.

Detailed Description

Fig. 1 shows a longitudinal section of an artery 1 which can be a coronary artery presenting a stricture or stenosis. During a first intervention, a catheter bearing an inflatable balloon at the end, was inserted into the artery until its balloon reached the stenosis. The balloon was then inflated with a fluid pumped in through the catheter. The inflated balloon pushed the arterial wall back and removed the stenosis. Since an inflated balloon blocks the artery, it had to be quickly deflated.

The inflating and deflating operation of the balloon may have been repeated several times. Subsequently, the balloon and catheter were withdrawn. During these operations, the internal wall of the artery, called intima, suffered some detachments 2 which, if not repaired, could block the artery and result in the death of the patient.

A device according to the present invention is depicted in the Figures and it can be advantageously used to facilitate repair of the detachments 2. It includes a removable endo-arterial prosthesis intended to reduce the risks caused by the detachments 2 by applying the detached flaps of wall against the artery long enough for cicatrization to take place.

Fig. 1 shows a device according to this invention in its elongated shape which makes it possible to introduce or withdraw it from the artery.

Fig. 2 represents a device according to the invention in its deployed form in which it is widened so that it presses the detached wall flaps against the artery.

A device according to the invention includes a deformable cuff 3 made of a net of twisted and interlocked wires which could, for instance, be of stainless steel wires or of any other material having equivalent properties of compatibility with the blood. The deformable cuff 3 is fixed to the end of

a small flexible tube 4 which has a diameter on the order of a few millimeters and serves as catheter. The distal end of the deformable cuff 3 is fixed to a small muff 5 on which a small flexible axial rod 6 is mounted which precedes the deformable cuff 3 and serves as guide for the latter along the artery.

A device according to Figs. 1 and 2 includes, in addition, an axial wire 7 of the piano-wire type which is fixed to the distal end of cuff 3, passes through the latter and extends the entire length of the catheter 4.

The catheter is preferably equipped at its proximate end with a funnel 4a of a known kind, for example, a funnel of the "LUER-LOCK" type. Wire 7 passes through the connection 4a, so that its end is accessible outside the catheter.

The practical application of a device according to Figs. 1 and 2 is the following:

The catheter bearing at its end a deformable cuff 3 which is fully elongated as shown in Fig. 1 and which therefore has a very small cross section is introduced into the artery. The progress of cuff 3 is controlled by radiography. When it reaches the area of the former stenosis, the end of wire 7 is pulled while the catheter is held in place in the artery. The pull exerted on the wire has the effect of bringing the distal end of cuff 3 close to its proximal end.

The cuff dilates as shown in Fig. 2 and comes to rest against the arterial wall, thus pressing the detached flaps back against the wall. Cuff 3 is left in this position for as long as one or more hours, since the blood can freely circulate through the mesh openings of the cuff which, at that time, are open. When it is deemed that sufficient time has elapsed for the flaps to adhere again to the wall, the outer end of wire 7, which is stiff enough not to bend, is pushed, thereby causing the distal end 5 of cuff 3 to move away, so that the cuff is again in its elongated position. The catheter 4, wire 7 and cuff 3 are then withdrawn together from the artery.

Fig. 3 is a larger scale axial section view of the proximal end of the deformable cuff 3. In this Figure the flexible tube or catheter 4 and the axial wire 7 are clearly seen.

Wires 8 which make up the end of the deformable cuff 3 are unraveled, inserted and fixed parallel to the axis between the end of tube 4 and a second tube 9 which is placed inside the latter and in which wire 7 runs freely. Tube 9 should preferably extend over the entire length of tube 4. The ends of wires 8 are glued between tube 4 and tube 9. A thermo-shrinkable sleeve 10 is preferably slipped over the proximal end of the cuff and then heat-shrunk to it.

In Fig. 3 it can be seen that the proximal end of the deformable cuff 3, which is fixed to catheter 4 and to the internal tube 9, slides freely over pull

wire 71.

Fig. 4 shows another embodiment of a device according to the invention.

When an inflatable balloon is introduced into an artery to correct a stenosis, the intervention generally begins with insertion into the artery of a guide wire of piano-wire type. The catheter is then slipped over this wire bearing at its end the inflatable balloon through which passes a small axial tube which engages the wire and follows it.

When the stenosis has been eliminated, the balloon is deflated and withdrawn from the artery, but the guide wire may be left in place for some minutes in case it becomes necessary to use the balloon again.

The device according to Fig. 4 is designed to be used in this case.

The numeral 11 represents a guide wire inserted into artery 1.

The device again includes a net 3 in form of a deformable cuff composed of interlocked wire mounted at the end of a small tube 4 and an axial wire 7 fixed to the distal end of the net which makes it possible to bring the latter closer to the proximal end in order to open the net or to push it farther away in order to close the latter. The distal end is located to the left in Fig. 4.

The device according to Fig. 4 also includes a small piece of tubing 12 which provides an axial opening or conduit 12a passing through the distal end of the cuff.

During application of the device according to Fig. 4, the end of the guide wire 11 which extends outside the artery and the patient is inserted through conduit 12a and then is passed through the mesh of the net so that it lies along the outside of tube 4. This permits the cuff to be guided on guide wire 11 until it reaches the zone where the stenosis had been located and previously corrected with an inflatable balloon.

During this insertion, the net 3 is in an elongated position. Once the device has arrived at the site, the axial wire 7 is pulled to open the net 3 and bring it into the position shown in Fig. 4. It may be left in this position for several hours. Subsequently, the net is re-folded by pushing on the axial wire 7 and pulling on tube 4, and the catheter is withdrawn from the artery along guide wire 11.

Figs. 5 and 6 represent another embodiment of a device according to the invention, including a netted cuff combined with an inflatable balloon.

To this date, inflatable balloons are used to correct the stenoses of the coronary arteries but only downstream from the common trunk, i.e. from the bifurcation of the circumflex and interventricular anterior arteries. They are used only very exceptionally to intervene on the common trunk because of the fact that detachments of the wall in the

common trunk occurring after the intervention with an inflatable balloon would deprive a large part of the heart of irrigation and thus cause almost instantaneous death.

Figs. 5 and 6 show a device according to this invention which would permit interventions on stenoses of the common trunk and also on strictures located below the latter or in other arteries.

The device according to Fig. 5 includes a deformable balloon 13 of the kind currently used for angioplasty mounted at the end of a flexible tube 14. An axial tube 15 passes through the balloon from one end to the other and is fixed to the latter by one or both of its ends.

Figs. 5 and 6 show an embodiment having two coaxial tubes 14 and 15. As a variation, a single tube divided into two conduits by an inner partition could alternatively be used.

Tubes 14 and 15 extend to the outside where they preferably end in a funnel of a known type, for example a "LUER-LOCK" funnel, which may be simple or include a derivation for the injection of fluid into the catheter. The axial tube 15 is adapted to receive the guide wire 11 which has previously been introduced into the artery. The interspace between tubes 14 and 15 is intended for injection or pumping of the inflation fluid into balloon 13.

The device also includes a net 3 in form of a cuff, comprising plaited wires surrounding the inflatable balloon, the distal end of which is fixed to the distal end of the balloon, while the proximal end slides freely on tube 14.

For the sake of clarity in the drawing, net 3 is shown partly cut away in Fig. 5. Net 3 is mounted at its proximal end to a flexible tube 16 which encloses tubes 14 and 15.

The steps of practical application are the following:

When a stenosis is to be corrected, a guide wire 11 is first introduced into the artery. The axial tube 15 is then inserted over it and the device according to Fig. 5 is then pushed along guidewire 11 in a stretched configuration, i.e. the balloon 13 is collapsed and net 3 is elongated. The progress is checked by radiography. Once the net and balloon are in place, fluid is pumped in between tubes 14 and 15 which inflates the balloon and, in turn, dilates the artery and eliminates the stricture.

The highly flexible and deformable net 3 does not hamper the inflation of the balloon, since it slides in relation to the latter. The inflation of the balloon causes the dilation of the net.

Once the stricture has been eliminated, the fluid is withdrawn and the balloon is deflated, but the net remains in place against the internal wall of the artery. If necessary, the net is pressed against the wall of the artery by pushing on tube 16 which is sufficiently rigid to transmit the thrust. The axial

tube 15 is held fast to immobilize the distal end.

The blood circulates through the mesh of the netting and the prosthesis may be left in this position for a time on the order of one to several hours which is more than enough for the eventual detachments of the inner arterial wall to heal.

Subsequently, tube 16 is pulled while keeping the axial tube 15 in place which has the effect of moving the two ends of net 3 further apart and putting the latter back into an elongated position, then the entire complex of the device is pulled out of the artery along guide wire 11.

In the embodiment according to Figs. 5 and 6, it is not necessary to use a wire to cause the deformation of cuff 3. The central tube 15 which is fixed to the distal end of the net and tube 16 which is fixed to the proximal end of the net are sufficient to permit moving these two ends toward or away from each other.

Claims

1. A removable endo-arterial device for repairing detachments of an arterial wall, comprising a deformable cuff (3) made of a netting of plaited and interlocked wires which is mounted at the end of a catheter (4, 16) and introduced into an artery (1) and which also includes means (7, 18) activated from the external end of said catheter (4) to bring two ends of said deformable cuff (3) closer together or move them farther apart in order to give it a wider shape which applies said cuff against the arterial wall or an elongated shape which permits said cuff and the catheter to be introduced into the artery or withdraw them from the latter.

2. The device according to claim 1, wherein said means to bring the two ends of said deformable cuff closer together or space them farther apart comprise a wire (7) of the piano-wire type, which is fixed to a distal end of said cuff while freely running through a proximal end of said cuff and extending through the entire length of the catheter.

3. The device according to either of claims 1 and 2, further including a piece of flexible guide rod (6) attached to the distal end of said deformable cuff.

4. The device according to either of claims 1 and 2, further including a guide tube (12) defining an axial conduit in the distal end of said deformable cuff, said guide tube being adapted to receive a guide wire (11) inserted into the artery and which returns through mesh openings in the netting.

5. The device according to claim 1, further including an inflatable balloon (13) mounted inside said deformable cuff at the end of an inflation tube (14) which runs inside a catheter (16) carrying said deformable cuff (3).

6. The device according to claim 5, further including an axial guide tube (15) which passes through said balloon, is fixed to the distal end of the latter and extends over the entire length of said catheter (16).

7. The device according to claim 6, wherein the distal ends of said balloon and said deformable cuff are fixed while the proximal end of said deformable cuff slides freely on said inflation tube (14).

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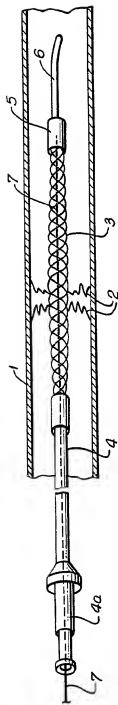


Fig. 1

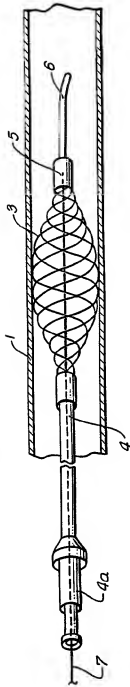


Fig. 2

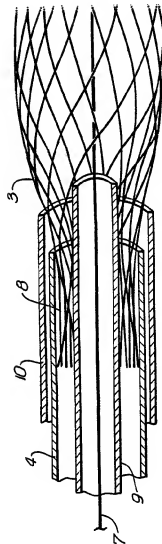


Fig. 3

03 21

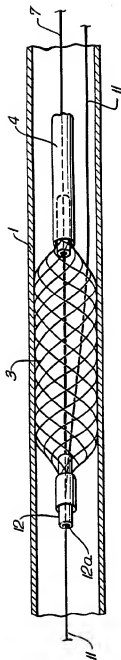


Fig. 4

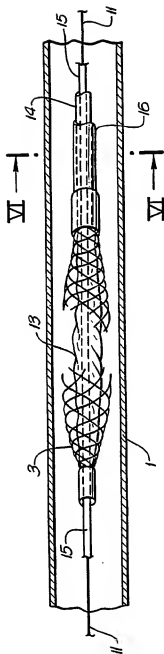


Fig. 5



Fig. 6



DOCUMENTS CONSIDERED TO BE RELEVANT		
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim
Y	US-A-4 650 466 (LUTHER) * Column 2, lines 44-61; figures *	1-4
Y	US-A-1 677 671 (COUNCILL) * Page 1, line 103 - page 2, line 20; figures *	1-4
Y	FR-A-2 454 293 (MEYER) * Page 1, lines 16-22; figure 3 *	4
A	DE-A-3 532 653 (KALTENBACH) * Column 2, lines 25-29 *	1
A	EP-A-0 183 372 (CAPONIGRO) * Page 10, lines 15-21; figures 3,4 *	1,5
P,A	EP-A-0 274 846 (ROSENBLUTH) * Column 8, line 57 - column 9, line 3 *	1,5
A	EP-A-0 186 267 (OSBORNE)	
		TECHNICAL FIELDS SEARCHED (Int. Cl.4) A 61 B A 61 F A 61 M
The present search report has been drawn up for all claims		
Place of search THE HAGUE	Date of completion of the search 28-03-1989	Examiner GLAS J.
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document		



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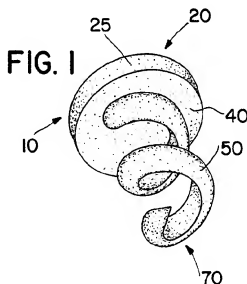
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64 Spiral surgical tack.

57 A surgical tack for use in surgical procedures. The surgical tack has a base member (25) and a distally extending spiral member having a distal piercing point (58). The spiral member forms a spiral. The tack may be used to fasten tissue, sutures, or medical devices to tissue.



Technical Field

The field of art to which this invention relates is surgical devices, more particularly, surgical tacks.

Background Art

Surgical staples are well known in the surgical arts. These staples have been widely used by surgeons to approximate incisions and wounds. Surgical staples have proven to be a useful alternative available to the medical practitioner in lieu of conventional sutures.

Surgical staples are often used in various surgical procedures. For example, when performing a surgical procedure to repair an inguinal hernia, one common technique is to affix a biocompatible surgical mesh over the site of the inguinal hernia. This is typically done by stapling the surgical mesh to the tissue and muscle surrounding the site of the hernia. The staples used in this procedure are, typically, conventional metal staples made from stainless steel, titanium, tantalum, or the like. There are several disadvantages associated with the use of metal staples in such a procedure. One obvious disadvantage is that the metal staples may remain inside of the patient indefinitely. In addition, it is not uncommon for a nerve to be entrapped and compressed by a metal staple. It is believed that this may cause residual pain in the patient. In order to alleviate such pain, a subsequent operation may be required to remove and/or replace the staples.

Another disadvantage of conventional staples is that the holding power of such conventional staples is limited by the size of the staple wire and the stiffness and mechanical properties of the material. A larger and/or stiffer metal staple is harder to bend around an anvil of a conventional surgical apparatus, and therefore limited in its strength. In some cases conventional metal staples may pull out of tissue because they are not strong or large enough.

The use of absorbable staples may help to overcome these problems and eliminate the need for additional surgery since, for example, an absorbable staple would absorb over time, thereby relieving any pressure upon a compressed nerve. Although absorbable staples are known in this art, such staples typically require access to both sides of a tissue site since they typically consist of an upper section having a crown and legs and a lower receiver. The lower receiver engages and locks the legs of the staple. Therefore, the absorbable staples known in the art are typically not usable in surgical procedures such as repair of an inguinal hernia where there is only access to one side of the tissue. Another type of absorbable staple which does not require a lower receiver is a three-piece staple described in commonly assigned, co-pending United States Patent Application

Serial No. 146,755 filed on November 2, 1993 which is incorporated by reference.

There is a need in this art for surgical fastening devices which do not require a second separate piece or receiver to lock or maintain the fastener in place in tissue, which can be applied and secured from one side of a tissue site in an endoscopic or open surgical procedure, and which overcomes the disadvantages associated with conventional surgical staples.

Disclosure of the Invention

Therefore, it is an object of the present invention to provide a surgical fastener which does not require an additional member to lock or maintain the fasteners in tissue.

It is a further object of the present invention to provide a surgical tack which easily attaches either tissue to tissue, sutures to tissue, or surgical devices such as mesh to tissue.

It is yet a further object of the present invention to provide a surgical tack which can be used for attachment wherein the tack is inserted from a single side of the tissue.

It is still yet a further object of the present invention to provide a method of attaching tissue using a surgical tack.

Accordingly, a surgical tack for use in surgical procedures is disclosed. The surgical tack comprises a base member having a top and a bottom. An optional suture mounting member may extend from the base member. A member extends from the bottom of the base member. The member is formed into a spiral having a longitudinal axis and a plurality of loops separated by spaces. The member has a proximal end and a distal end. Preferably, the member has at least one outwardly extending edge. The member has a piercing point extending from its distal end. The piercing point may extend substantially parallel to the longitudinal axis or may be angulated with respect thereto. The member may have various types of cross-sections including a semi-cylindrical cross-section, a triangular cross-section, a parabolic cross-section, and a rectangular cross-section. The spiral consists of at least one coil. The coils may have a circular configuration or square, triangular or polygonal configurations. Optionally, various shaped cavities may be formed into the top surface of the base member to facilitate driving of the tack, e.g., slots, etc.

Yet another aspect of the present invention is a method of fastening tissue. The method comprises inserting the above-described tack into one side of the tissue. The tack may be used to fasten tissue to tissue, sutures to tissue, or medical devices to tissue including surgical meshes.

Other features and advantages of the invention will become more apparent from the following description and accompanying drawings.

Brief Description of the Drawings

FIG. 1 is a perspective view of the surgical tack of the present invention.

FIG. 2 is a side view of the surgical tack of the present invention.

FIG. 3 is a bottom view of the surgical tack of the present invention illustrating a member extending distally from the bottom of the base member to form a spiral.

FIG. 4 is a cross-sectional view of the surgical tack of FIG. 3 taken along view line 4-4.

FIG. 5 is an illustration of a perspective view of an alternate embodiment of the surgical tack of the present invention having a hexagonal base member.

FIG. 5A is a cross-sectional view of the spiral member of the tack of FIG. 5 taken along view line 5A-5A illustrating the triangular cross-section of the member.

FIG. 6 is a perspective view of an alternate embodiment of a surgical tack of the present invention.

FIG. 6A is a cross-sectional view of the spiral member of the tack of FIG. 6 taken along view lines 6A-6A illustrating a parabolic cross-section of the member.

FIG. 7 is a perspective view of an alternate embodiment of the tack of the present invention.

FIG. 7A is a cross-sectional view of the spiral member of the tack of FIG. 7 illustrating a rectangular cross-section.

FIG. 8 is a perspective view of the base member of the tack of FIG. 1 having a slotted cavity for receiving the tip of a conventional screw driver.

FIG. 9 is a perspective view of the base member of the tack of FIG. 1 having a cavity for receiving the tip of an Allen wrench.

FIG. 10 is a perspective view of the base member of the tack of FIG. 1 having a cavity for receiving the tip of a Phillips screw driver.

FIG. 11 is a perspective view of the base member of the tack of FIG. 1 having a cavity for receiving the tip of a Torx screw driver.

FIG. 12 is a bottom view of an alternate embodiment of the tack of the present invention wherein the spiral has square coils.

FIG. 13 is a bottom view of an alternate embodiment of the tack of the present invention wherein the spiral has triangular coils.

FIG. 14 is a bottom view of an alternate embodiment of the tack of the present invention wherein the spiral has circular coils which vary in diameter along the longitudinal axis of the spiral.

FIG. 15 is a bottom view of an alternate embodiment of the tack of the present invention wherein the spiral member is formed into a spiral having circular coils and the piercing point is perpendicular to the longitudinal axis of the spiral.

FIG. 16 is a side view of the tack of FIG. 1 having

the ends of surgical sutures mounted therein.

FIG. 17 is a side view of the tack of FIG. 1 illustrating a surgical suture tied to the spiral member.

FIG. 18 illustrates an alternate embodiment of the tack of the present invention having a suture mounting means extending from the top of the base member.

FIG. 19 illustrates an alternate embodiment of the tack of the present invention having a base member having crossed beam members which can also be used to mount a suture.

Best Mode for Carrying Out The Invention

The surgical tacks of the present invention are illustrated in FIGS. 1-19. Referring first to FIGS. 1-4, the tack 10 is seen to have a base member 20. The base member 20 has top surface 30 and bottom surface 40 and side surfaces 25 connecting the top surface 30 and the bottom surface 40. The base member 20 preferably has a circular disk-like shape, however, other shapes may be utilized including rectangular, square, hexagonal, and polygonal. The base member 20 may be solid or have a hole through it to facilitate the manufacture of a distally extending spiral. The top surface 30 of the base member 20 may have features incorporated therein to facilitate the driving of the tack (see FIGS. 8-11). These features may consist of cavities such as cavities 31, 32, 33, and 34, to accept slotted screw drivers, Allen, Phillips, or Torx screw drivers, respectively, or square or other tools to impart rotation to the tack 10. A distally extending spiral member 50 is seen to extend down from the bottom surface 40 of the base member 30. The distally extending member 50 preferably is shaped to form a spiral 60 having coils 65 of constant size, although the size of the coils may vary, if desired, along the longitudinal length of the spiral. The coils 65 are seen to be separated by gaps which are constant or which vary along the longitudinal axis of the spiral. Member 50 is seen to have proximal end 52 and distal end 54. Extending from the distal end 54 is the piercing tip 58. The piercing tip 58 may have a conventional sharp piercing point configuration sufficient to effectively penetrate through tissue. The piercing tip 58 may also have a blunt configuration effective to pierce tissue. The piercing point 58 may be aligned parallel to the longitudinal axis of the spiral 60, or be pointed obliquely off the axis of the spiral to facilitate penetration of tissue. The member 50 or tip 58 may have one or a plurality of barbs that increase the holding power of the tack in tissue. The member 50 is seen to have, preferably, at least one edge 59. Referring to FIG. 4, the member 50 is seen to have a substantially semi-cylindrical cross-sectional configuration with two outer edges 60. As seen in FIGS. 3 and 4, a passage 70 is contained within the spiral 60.

An alternate embodiment of the surgical tack 10

of the present invention is seen in FIG. 5. The tack 100 is seen to have a hexagonal base member 105 having top 110 and bottom surface 115. Side surfaces 117 connect top surface 105 with bottom surface 115. Distally extending spiral member 120 is seen to extend downwardly from the bottom surface 115 forming spiral 128. As seen in FIG. 5A, the member 120 is seen to have a triangular cross-section and three outer edges 122. Point 126 is seen to extend from the distal end 124 of the member 120.

Yet another embodiment of the present invention is seen in FIG. 6. The tack 130 is seen to have a hexagonal base member 131 having top surface 132, bottom surface 134 and connecting side surfaces 136. Extending distally from the bottom surface 134 of the base member 131 is the spiral member 140 forming spiral 149. Member 140 is seen to have distal end 142 and piercing point 144 extending from distal end 142. Referring to FIG. 6A, the member 140 is seen to have a substantially parabolic cross-section having outer edges 146.

Another embodiment of the tack of the present invention is seen in FIG. 7. The tack 150 is seen to have base member 151. The base member 151 is seen to be substantially hexagonally shaped. The base member 150 is seen to have upper surface 152, lower surface 154 and side connecting surfaces 156. Extending distally from the bottom 154 of the base member 150 is the spiral member 160 forming spiral 169. The member 160 is seen to have edges 162, distal end 164, and point 166 extending from the distal end 164. Referring to FIG. 7A, the member 160 is seen to have a generally substantially rectangular cross-section having outer edges 166.

The spiral member of the tacks of the present invention may be formed into various shaped spirals. For example, the tack 10 of FIG. 1 is seen to have a spiral 60 which is helical in shape having circular coils of constant diameter. In addition, the spirals of the tacks of the present invention may have various other geometric configurations. For example, FIG. 12 illustrates a tack 200 having a base member 210 and a spiral member 215 formed into a spiral 217 wherein the coils 220 have a square configuration. The piercing point 225 is directed perpendicular to the longitudinal axis of spiral 217.

Referring to FIG. 13, a tack 230 is seen to have a base member 231 and a distally extending spiral member 235 forming a spiral 236 having triangularly shaped coils 238. The piercing point 240 is seen to extend perpendicular to the longitudinal axis of the coil 236. Another embodiment of a spiral is seen in FIG. 14. The tack 250 is seen to have base member 251 and distally extending spiral member 252 forming spiral 253 having coils 254 which are generally circular in configuration and decrease in diameter along the longitudinal length of the spiral 253. The point 255 is seen to be generally aligned with the longitudinal axis

of spiral 253. Referring to FIG. 15, an alternate embodiment of the tack 10 of FIG. 1 is illustrated. The tack 260 is seen to have base member 261 and downwardly extending spiral member 262 forming spiral 263 having coils 264 of circular configuration and constant diameter. The piercing point 265 is seen to be directed substantially perpendicular to the longitudinal axis of the spiral 263.

Sutures may be affixed to the tacks of the present invention in various manners. Referring to FIG. 16, a tack 310 is seen to have a base member 320, having top 330 and downwardly extending spiral member 350. Two ends of a suture are seen to be mounted in the base member 320 extending upward from the top 330 of the base member 320. The sutures may be mounted in conventional manners including co-molding, bonding, mechanical fasteners, adhesives, welding and the like.

An alternate suture mounting configuration is seen in FIG. 17. In FIG. 17, a suture 300 is seen to be tied about the proximal end of distally extending spiral member 50 of a tack 10 of the present invention adjacent to the base member 20.

An alternate configuration for mounting a suture to a tack of the present invention is seen in FIG. 18. A tack 400 is illustrated having base number 420 having a top surface 421 and a bottom surface 422. Extending downwardly from the bottom surface 422 is a spiral member 450. Extending upwardly from surface 421 of the base number 420 is the suture mounting member 430 having suture receiving hole 431. The suture 300 is threaded through suture receiving hole 431. Yet another embodiment of a tack having a suture mounting configuration is seen in FIG. 19. The tack 460 is seen to have a base number 470 consisting of outwardly extending members 480 each having distally extending end sections 485. The tack is seen to have distally extending spiral member 490 extending from the bottom surface 481 of the base member 470. Suture 300 is mounted about the base number 470 and is contained by the downwardly extending retention members 485.

The surgical tacks of the present invention may be used to approximate tissues, to hold a medical device to the surface of tissue including, for example, a surgical mesh, or to anchor tissue to an anatomic site. The tacks of the present invention can be manufactured in small sizes useful in endoscopic surgical techniques. The tacks resist large removal forces. In addition, the tacks can be applied when the surgeon has access to only one side of a tissue site. The tacks of the present invention tend to be atraumatic because unlike staples, they do not compress tissue and they only puncture at one site per fastener versus typically two per site for conventional staples and fasteners. It is known that the use of staples, which squeeze tissue when they are applied or fired, may in certain instances cause ischemia, with resultant nec-

rosis depending upon the pressure exerted by the staple. In addition, most staples are made of non-absorbable materials and remain behind even after the critical healing period.

The tacks of the present invention may be manufactured from absorbable or non-absorbable materials. It is particularly preferred to manufacture the tacks of the present invention from absorbable materials which are absorbed by the body over the course of the healing process thereby eliminating the fastener when it is no longer needed to perform its function approximating or fastening tissue.

The tacks of the present invention, such as tack 10, are used in the following manner. The tack is grasped by an appropriate grasping instrument, such as a conventional surgical grasper, screw driver, nut driver, allen wrench, or endosurgical grasper or may even be applied by hand. The point 58 of the tack 10 is pressed against the outer surface of the tissue. Then, the tack is rotated to set the curved member into the tissue. The tack may be used on various types of tissues ranging from soft muscle, fascia, or fat to hard ligaments and tendons.

The tacks of the present invention 10 will have a spiral member having a cross-sectional configuration sufficiently large to effectively anchor the tack 10 in tissue when formed into a spiral. For example, the tack 10 may have a spiral member 50 having a circular cross-section with a diameter of about 0.010 inches to about 0.075 inches. The length of the spiral and the size of the coils will depend upon the particular application and the characteristics of the materials of construction. The mechanical characteristics of the materials of construction, e.g., stiffness, will be sufficient to effectively enable the tack to penetrate tissue without deforming. The major dimension of the coils of the spiral will be appropriate for the tissue in which the tack is being anchored, and will be sufficient to effectively provide the required holding power of the tack, and may depend upon the method with which the tack is being applied. For example, the diameter of the coils may vary from about 0.125 inches to about 0.250 inches. The length of the spiral and the number of coils of the spiral will depend on the holding power required and the depth of tissue in which the tack will be anchored as well as the type of tissue. The number of coils can be any amount greater than one-half. One skilled in the art will readily appreciate minimal routine experimentation will readily lead to a determination of the optimal spiral length, coil major dimensions, and number of coils for each particular application.

The surgical tacks of the present invention may be made from either conventional bioabsorbable materials or conventional non-absorbable materials, combinations thereof and equivalents thereof. Examples of absorbable materials include homopolymers and copolymers of lactide, glycolide, trimethylene

carbonate, caprolactone, and p-dioxanone and blends thereof. Of particular utility are the following two blends:

(1) the blend of poly(p-dioxanone) and a lactide/glycolide copolymer, as disclosed in U.S. Patent No. 4,646,741 which is incorporated by reference.

(2) the glycolide-rich blend of two or more polymers, one polymer being a high lactide content polymer, and the other being a high glycolide content disclosed in U.S. Patent No. 4,889,119 which is incorporated by reference.

The tacks may also be made from conventional non-absorbable, biocompatible materials including stainless steel, titanium, polymers, composites and the like and equivalents thereof.

The following example is illustrative of the principals of practice of the present invention, although not limited thereto.

EXAMPLE I

A patient is prepared for surgery using conventional surgical preparatory techniques. The patient is anesthetized with a sufficient dose of a conventional anaesthesia to induce an effective anaesthetized state. An incision is made into the patient's abdominal cavity in order to access the site of an inguinal hernia using conventional surgical techniques. After the site of the inguinal hernia is prepared using conventional surgical techniques, a piece of a conventional, biocompatible surgical mesh is placed over the site of the inguinal hernia. Absorbable surgical tacks 10 of the present invention are applied by grasping the tacks 10 with an appropriate surgical grasping instrument and placing the tacks 10 into position proximal to the tissue to be fastened. The tacks 10 are made from a conventional absorbable polymeric material. The piercing points 58 of the spiral members 50 are positioned substantially perpendicular to the surface of the tissue. The tack 10 is then pushed distally through the mesh until the tip 58 pierces the tissue. The tack 10 is then rotated which causes it to move distally into the tissue until the bottom surface 40 of the base member 20 contacts the mesh.

After the mesh is secured by using a sufficient number of tacks 10 to effectively affix the mesh, for example about fifteen, the inguinal hernia procedure is completed in a conventional manner and the incision in the wall of the abdominal cavity is closed using conventional surgical sutures. The surgical tacks 10 maintain the surgical mesh over the site of the inguinal hernia and are absorbed by the patient's body over time.

Although this invention has been shown and described with respect to detailed embodiments thereof, it will be understood by those skilled in the art that various changes in form and detail thereof may be

made without departing from the spirit and scope of the claimed invention.

the tack into tissue.

Claims

1. A tack for use in a surgical procedure, the tack comprising:

a base member having a top surface and a bottom surface;

a spiral member extending from the bottom of the base member, said spiral member having at least one outer edge, the spiral member having a distal end, wherein the spiral member forms a spiral, said spiral comprising at least one coil, a longitudinal axis and an interior passage; and,

piercing means extending from the distal end of the spiral member.

2. The tack of Claim 1 wherein the spiral member has a substantially semi-cylindrical cross-section.

3. The tack of Claim 1 wherein the spiral member has a substantially triangular cross-section.

4. The tack of Claim 1 wherein the spiral member has a substantially parabolic cross-section.

5. The tack of Claim 1 wherein the spiral member has a substantially rectangular cross-section.

6. The tack of Claim 1 wherein the coil has a circular configuration.

7. The tack of Claim 1 wherein the coil has a triangular configuration.

8. The tack of Claim 6 wherein the spiral comprises a plurality of circular coils wherein the coils have coils which decrease in diameter along the longitudinal axis of the spiral.

9. The tack of Claim 1 wherein the piercing means comprised of a point extending from the distal end of the spiral member.

10. The tack of Claim 9 wherein the point extends substantially parallel to the longitudinal axis of the spiral.

11. The tack of Claim 9 wherein the point extends substantially perpendicular to the longitudinal axis of the spiral.

12. The tack of Claim 1 further comprising means mounted in the base member to facilitate driving

13. The tack of Claim 1 further comprising a surgical suture mounted thereto.

14. The tack of Claim 1 further comprising suture mounting means extending from the top surface of the base member.

15. The tack of Claim 14 wherein the suture mounting means comprises a proximally extending member having a suture receiving hole therein.

16. A tack of Claim 1 wherein the base member has a circular configuration.

17. A tack of Claim 1 wherein the base member has a polygonal configuration.

18. The tack of Claim 1 wherein the base member comprises two intersecting perpendicular members having outer ends and distally extending retention members extending from the outer ends.

19. The tack of claim 12 wherein the driving means comprises a cavity in the top surface of the base member configured to accept a driving tool means.

20. A method of surgically fastening tissue comprising:

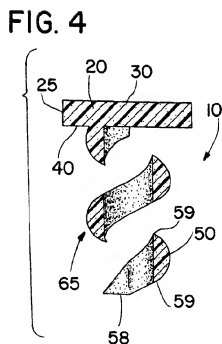
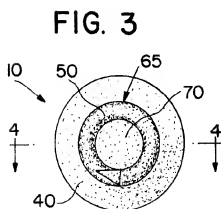
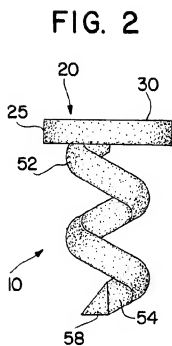
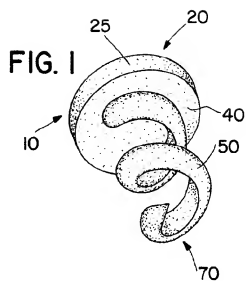
inserting a surgical tack into one side of a section of tissue, wherein the tack comprises:

a proximal base member having a top surface and

a bottom surface;

a distal spiral member extending from the bottom of the base member, said spiral member having at least one outer edge, the spiral member having a distal end, wherein the spiral member forms a spiral, said spiral comprising at least one coil, a longitudinal axis and an interior passage; and,

piercing means extending from the distal end of the spiral member.



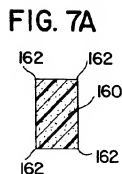
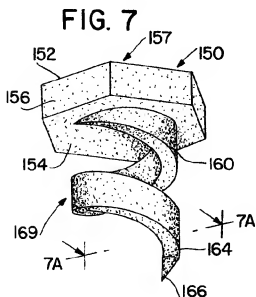
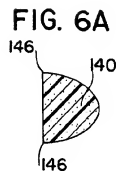
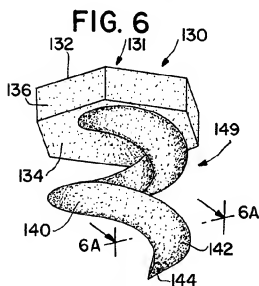
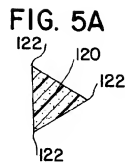
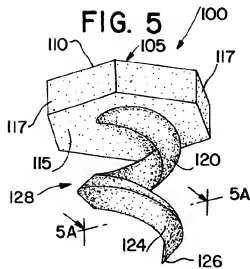


FIG. 8

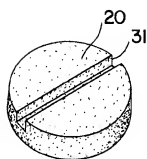


FIG. 9

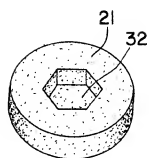


FIG. 10

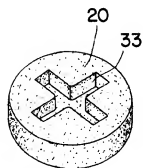


FIG. 11

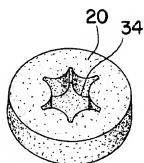


FIG. 12

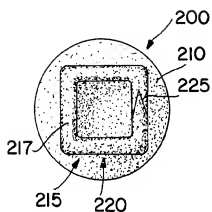


FIG. 13

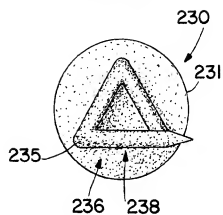


FIG. 14

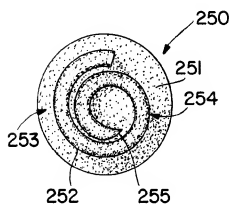


FIG. 15

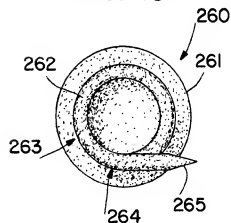


FIG. 16

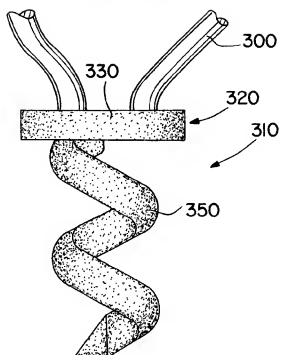


FIG. 17

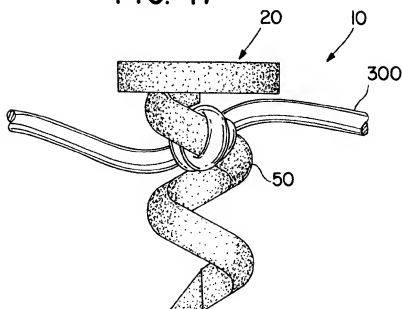


FIG. 18

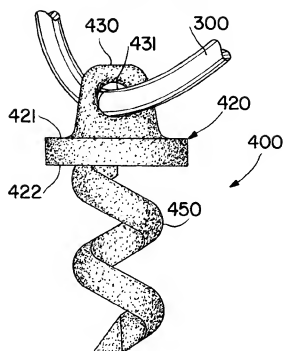
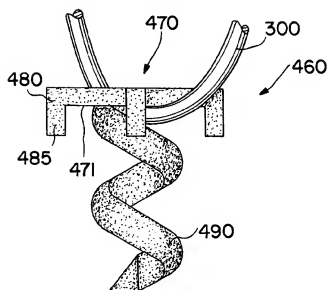


FIG. 19





European Patent
Office

PARTIAL EUROPEAN SEARCH REPORT

Application Number

which under Rule 45 of the European Patent Convention EP 95 30 0207
shall be considered, for the purposes of subsequent
proceedings, as the European search report

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (In C.L.A.)
X	EP-A-0 374 088 (GEBRUDER SULZER AG ET AL.) * column 2, line 20 - column 3, line 12; figures 1,4-6 *	1-7, 11-17, 19	A61B17/04 F16B25/00 A61B17/56
Y	---	8-10, 13-15	
X	GB-A-2 186 937 (TEXTRON INC.) * page 3, line 44 - line 62 * * page 3, line 119 - line 128; figures 8,12 *	1,6,12, 16,19	
Y	---	8-10	
Y	US-A-5 217 486 (RICE ET AL.) * figures 1,2 *	13-15	

			TECHNICAL FIELDS SEARCHED (In C.L.A.)
			A61B F16B
INCOMPLETE SEARCH			
<p>The Search Division considers that the present European patent application does not comply with the provisions of the European Patent Convention to such an extent that it is not possible to carry out a meaningful search into the state of the art on the basis of none of the claims</p> <p>Claims searched completely: 1-19 Claims searched incompletely: Claims not searched: 20 Reasons for the limitation of the search:</p> <p>Claim 20 refers to a method for treatment of the human or animal body by surgery. (Art. 52(4) EPC)</p>			
Place of search BERLIN		Date of completion of the search 1 March 1995	Examiner Roland, A
CATEGORY OF CITED DOCUMENTS		<p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application I : document cited for other reasons</p> <p>A : technological background O : non-written disclosure P : intermediate document</p> <p>§ : member of the same patent family, corresponding document</p>	
<p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category</p>			

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(54) Surgical helical fastener with applicator

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Agrafe chirurgicale hélicoidale avec applicateur

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US-A- 5 163 343	US-E- R E28 932

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Description

BACKGROUND OF THE INVENTION

[0001] This invention relates to surgical fasteners and their associated applicators, and more particularly, surgically fastening material to tissue.

[0002] Fasteners have been used surgically to eliminate the need for suturing, which is both time consuming and inconvenient. In many applications the surgeon can use a stapler apparatus, i.e., a fastener implanting device loaded with surgical fasteners to accomplish in a few seconds what would have taken many minutes to perform by suturing. This reduces blood loss and trauma to the patient.

[0003] conventional surgical fasteners have been in the form of ordinary metal staples, which are bent by the delivery apparatus to hook together body tissue. Typically, conventional staples comprise a pair of legs joined together at one end by a crown. The crown may be a straight member connecting the legs or may form an apex. Moreover, the legs may extend substantially perpendicular from the crown or at some angle therefrom. Respective of the particular configuration, however, conventional staples are designed so that they may be deformed to hold body tissue.

[0004] Accordingly, the stapler applicators have conventionally embodied structure functioning to project the conventional staple into tissue as well as to deform the staple so that it is retained against the tissue. Generally speaking, typical applicators include an anvil cooperating with means to eject the conventional staple from the applicator. In some applications, access to the body tissue from two opposite directions is available and the anvil can operate to deform the legs of the staple after they have passed through the body tissue. In applications where access to the tissue is from only one direction, the anvil may deform the crown of the conventional staple so that its legs will project into the body tissue in a fashion so as to hold the staple against the tissue.

[0005] Since conventional staples require deformation and must cooperate with applicators having an anvil or other means to deform the staples, conventional applicators typically comprise complex structures and can be prohibitively expensive. Conventional applicators must embody structure functioning to not only eject the fasteners but to do so in a manner so that the fastener deforms properly and timely.

[0006] In some applications, conventional applicators must be equipped with structure functioning to move the anvil into and out of position so that when the fastener is ejected from the applicator, the anvil is properly positioned and once fastener deformation is complete, moves out of position, thereby allowing the process to be repeated. Moreover, the anvil must be formed into a proper configuration so that fastener deformation can be repeated accurately. Further, the force between the fastener and the anvil must be controlled so that repeat-

ed deformation is accomplished. The objectives of many inventions in this field have been to accomplish these goals by the simple manipulation of a single lever. It is to be appreciated, therefore, that the fastener applicators have become complex and expensive instruments.

[0007] Two part fasteners have also been conventionally utilized, where a barbed staple is used in conjunction with a retaining piece to hold the staple in place. Typically, the two part staple comprises a crown or backspan and two barbed prongs which are engaged and locked into a separate retainer piece. In use, the staple is pressed into the body tissue so that the barbs penetrate the tissue and emerge from the other side where they are then locked into the retainer piece. Retainers prevent the staple from working loose from the tissue. The two piece fasteners cannot be unlocked and are not removable.

[0008] Like other conventional applications, however, the two piece fasteners require the staple delivery apparatus to have access to both sides of the tissue. Thus, as with the other conventional applications, two piece fasteners are limited since they cannot be used where access to tissue is from one direction only.

[0009] In those situations where access to body tissues is limited to one direction, as in grafting procedures, deformable surgical fasteners have been conventionally employed. As mentioned previously, however, the applicators commonly used in these situations embody an anvil cooperating with a fastener to deform it and consequently, tend to be of a complex design.

[0010] Some advancements have been made in this area so that applicators functioning to attach grafts to tissue, for instance, are not required to embody an anvil and may, therefore, have a more simple design. In particular, it has been suggested in the art to employ fasteners with barbs, thereby, eliminating the need for deforming the fastener. These fasteners are limited, however, since the path created in the graft and tissue by the barbs as the fastener is pressed into the graft and tissue may allow the fastener to loosen its grip or to entirely back out of engagement. Moreover, due to their sole reliance upon barbs to retain tissue, the barb fasteners are further limited in that they may not have a great enough retentive surface area for securely holding tissue in place.

[0011] In WO-A-9014795 there are described various designs of suture device including a suture device made of bioabsorbable material having an elongate body member with a sharp distal end for penetrating tissue and means for locking the suture device in tissue to prevent forward and rearward movement. There is also described a suture device made of bioabsorbable material having a hinge-like joint for folding a distal portion at a precise location to be juxtaposed with a proximal portion for adjustable locking. Methods of using the suture devices for joining tissue sections, such as in tuboplasty, for closing anatomical lumens and for subcuticular suturing are also described.

[0012] In the quite unrelated field of surface coverings such as carpets, rugs, mats and the like it is known from US-A-5,163,343 to provide a system for fastening at least a pair of plies of fabric together utilizing a helical member having a body portion of a certain pitch. The helical member also includes a sharpened tip and an end portion with a loop which lies in a plane which intersects the helical path of the helical member. A tool constructed with a gripping portion and a hollow portion connected to the same is employed to turn the helical member through the adjacent plies of fabric.

[0013] Nevertheless to circumvent or overcome the problems and limitations associated with conventional surgical fasteners and applicators, a simple applicator that dispenses a surgical fastener having high surface area for retentive contact with tissue and that can be delivered into body tissue from one direction may be employed.

SUMMARY OF THE INVENTION

[0014] According to the present invention there is provided a system for ligating tissue or attaching an implantable device, the system comprising a plurality of continuous helical coils each having a distal end, a proximal end and a first helical coil section at said distal end, said distal end being configured to pierce tissue and said proximal end being configured to receive and translate rotational forces; and an applicator for applying rotational forces to said proximal end of said continuous helical coils, said applicator including ratcheting means so that only a single continuous coil may be completely ejected out of the applicator at a time.

[0015] Thus the invention includes a plurality of surgical fasteners and an applicator used in delivering the fasteners into body tissue. The fasteners and applicator may be used in a number of medical procedures including ligating tissue, hernia mesh repair, bladder neck suspension, and in conjunction with implant drug delivery systems or procedures involving positioning of surgical or implantable devices in a patient's body.

[0016] In a preferred embodiment the continuous helical coils are longitudinally collapsible and expandable. At the distal ends of the helical fasteners is a point for enhancing penetration into tissue. The proximal ends of the helical fasteners have a T-bar which sections the diameter of the fastener, thereby providing a surface for receiving and transmitting longitudinal and rotational forces so that the fasteners may be driven into tissue by a corkscrew action. The pitch and length of the helical fasteners may vary upon the application as can their diameter and the configuration of the most proximal and distal coils comprising the fastener. Additionally, the material selection and fastener stiffness may be selected with a particular application in mind.

[0017] In another embodiment, the surgical fasteners may comprise a double continuous helical coil that is also longitudinally collapsible and expandable and may

embody various configurations depending upon the application. Moreover, the distal end of the double helical fasteners may comprise two points for enhancing penetration into tissue and their proximal ends may comprise a connector bar which connects the two helices as well as sections the diameter of the double helical fastener. In yet another embodiment, the surgical fasteners may further comprise a pivot post extending through the center of the fastener and operating to provide the fastener with a stable pivot. In any of the embodiments, one or more barbs may be employed near the point to enhance anchoring characteristics.

[0018] In a preferred embodiment the fastener applicator includes a proximal portion and a distal portion. The proximal portion is preferably fabricated to be a "reusable" component and the distal portion a "disposable" component.

Alternatively, both the distal and proximal portion can be made disposable. The distal portion is elongate and embodies an outer tube housing an inner rotator, a lock clip/indicator and a load spring. The proximal portion includes a handle. In the preferred embodiment of the distal portion, a thread form comprising an interlock spring is provided within the outer tube. The rotator includes a structure running longitudinally along its length that functions to receive the T-bar or connector bar of the fasteners and in this way, the rotator holds a plurality of fasteners. The load spring applies a force against the lock clip/indicator operating to bias the plurality of springs distally within the outer tube and towards the nose piece. The thread form functions to engage the coils of the helical fasteners and when rotating the rotator, a fastener is driven from the distal end of the applicator. In other embodiments of the applicator, the distal end has various other structures functioning to engage the coils of the fasteners and to drive them from the distal end of the applicator. In one other embodiment, the distal end comprises a nose piece protrusion for engaging the fasteners.

[0019] In order to cause the rotator to rotate, the proximal portion of the applicator has a handle and an actuator cooperating with the rotator. In a preferred embodiment, the proximal portion of the applicator embodies a lever pivotally attached about a midpoint to the handle. A first end of the lever is configured to be gripped by hand and a second end is adapted to engage a nut driver. The nut driver travels along a helical lead screw which is connected to the rotator. When the lever is squeezed by hand the nut driver travels along the lead screw causing it to rotate, and through the connection of the lead screw to the rotator, the action of the lead screw causes the rotator to rotate.

[0020] Further, the lever comprises a midsection extension. Pivotally attached to the midsection extension of the lever is a spring loaded pawl adapted to releasably engage gear teeth formed in the interior of the handle. The spring loaded pawl prohibits the lever from backstroking until it has been completely depressed. Upon

complete depression of the lever, the pawl clears the gear teeth and the spring, biasing the pawl, rotates the pawl away from the teeth, thereby allowing the lever to return to its undepressed condition.

[0021] In another embodiment of the proximal portion of the applicator, the lever is pivotally attached at a first end to the handle, the second end being adapted to engage the nut driver. Further, rather than embodying a spring loaded pawl, this alternate embodiment of the proximal portion includes a clutch assembly or releasable connection between the lead screw and rotator and cooperating means to prohibit the lever from backstroking until it has been completely depressed.

[0022] Other features and advantages of the present invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings, which illustrate, by way of example, the principals of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023]

FIGURE 1 depicts a perspective view of a fastener of the present invention, illustrating a side view of a helical fastener.

FIG. 1A depicts another perspective view of the fastener of the present invention, illustrating an end view of the helical fastener.

FIG. 1B depicts a schematic view of a fastener of the present invention, illustrating a substantially collapsed helical fastener with a relatively small gap that has been partially inserted into tissue.

FIG. 1C depicts a schematic view of a fastener of the present invention, illustrating the helical fastener depicted in FIG. 1B completely inserted into tissue.

FIG. 1D depicts a schematic view of a fastener of the present invention, illustrating a substantially collapsed helical fastener with a relatively large gap that has been partially inserted into the tissue.

FIG. 1E depicts a schematic view of a fastener of the present invention, illustrating the helical fastener depicted in FIG. 1D completely inserted into tissue.

FIG. 1F depicts a perspective view illustrating an end view of the helical fastener of another embodiment of the present invention.

FIG. 2 depicts a perspective view illustrating a double helical fastener of another embodiment of the present invention.

FIG. 2A is a front view of the double helical fastener of FIG. 2.

FIG. 2B is side view of the double helical fastener of FIG. 2.

FIG. 2C is a top view of the double helical fastener of FIG. 2.

FIG. 3 is a perspective view illustrating another de-

sign of a double helical fastener of yet another embodiment of the present invention.

FIG. 3A is a front view of the double helical fastener of FIG. 3.

FIG. 3B is a side view of the double helical fastener of FIG. 3.

FIG. 3C is a top view of the double helical fastener of FIG. 3.

FIG. 4 is a perspective view illustrating a helical fastener with a central post of the present invention.

FIG. 5 depicts a schematic cross-sectional view of an applicator of the present invention, illustrating a side view of the applicator.

FIG. 6 is a schematic cross-sectional side view of a terminal end of the applicator.

FIG. 6A is a schematic cross-sectional end view of a terminal end of the applicator.

FIG. 7 is a schematic cross-sectional view of the terminal end of the applicator, illustrating the preferred embodiment of the terminal end.

FIG. 7A is a schematic cross-sectional end view of the preferred embodiment of the terminal end of the application shown in FIG. 7.

FIG. 8 is a schematic cross-sectional view of the terminal end of the applicator, illustrating another embodiment of the terminal end.

FIG. 8A is a schematic cross-sectional end view of the embodiment of the terminal end of the applicator shown in FIG. 8.

FIG. 9 is a schematic cross-sectional view of the terminal end of the applicator, illustrating yet another embodiment of the terminal end.

FIG. 9A is a schematic cross-sectional end view of the embodiment of the terminal end of the applicator shown in FIG. 9.

FIG. 10 is a schematic cross-sectional view of the terminal end of the applicator, illustrating still yet another embodiment of the terminal end.

FIG. 10A is a schematic cross-sectional end view of the embodiment of the terminal end of the applicator shown in FIG. 10.

FIG. 11 is a schematic cross-sectional view of the terminal end of the applicator, illustrating another embodiment of the terminal end.

FIG. 11A is a schematic cross-sectional end view of the embodiment of the terminal end of the applicator shown in FIG. 11.

FIG. 12 is a schematic cross-sectional view of the terminal end of the applicator, illustrating a further embodiment of the terminal end.

FIG. 12A is a schematic cross-sectional end view of the embodiment of the terminal end of the applicator shown in FIG. 12.

FIG. 13 is a schematic cross-sectional view of the terminal end of the applicator, illustrating a still further embodiment of the terminal end.

FIG. 14 is a schematic cross-sectional view of the terminal end of the applicator, illustrating still yet an-

other embodiment of the terminal end.

FIG. 15. is a schematic cross-sectional view of another applicator of the present invention, illustrating a side view of the applicator.

FIG. 16 is a schematic partial cross-sectional view of a releasable connection between the lead screw and rotator.

FIG. 16A is schematic representation of a distal end of the lead screw, illustrating an end view of the lead screw.

FIG. 16B is a schematic representation of the distal end of the lead screw, illustrating a side view of the lead screw depicted in FIG. 16.

FIG. 16C is a schematic representation of the proximal end of the rotator, illustrating a side view of the rotator.

FIG. 16D is a schematic representation of the proximal end of the rotator, illustrating an end view of the rotator depicted in FIG. 16B.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0024] As is shown in the drawings, which are included for purposes of illustration and not by way of limitation, the invention is embodied in a continuous helical fastener and an applicator therefor. The helical fastener has a high retentive surface area and the applicator has a simple design and functions to dispense the helical fasteners, without substantially deforming the fasteners, into body tissue, access to which is from one direction only. Some conventional fasteners require deformation to hold tissue and are consequently limited since they require complex applicators to attach them into tissue. Other conventional fasteners lack high retentive surface area for securely holding tissue. Still other fastener/applicator systems require access to tissue from two directions in order to accomplish attaching a fastener to tissue. Thus, the helical fastener and applicator of the present invention provides a superior means to attach fasteners to tissue.

[0025] One embodiment of the present invention (FIGS. 1, 1A and 5) is embodied in a helical fastener 10 which is attached to tissue by employing a novel applicator 12 which rotates the fastener 10 into tissue. The dimensions and physical characteristics of the helical fastener 10 are selected to insure a secure attachment of the fastener 10 to tissue. Similarly, the dimensions and physical characteristics of the applicator 12 utilized to dispense the fasteners 10 into tissue are dependent upon the application.

[0026] In a preferred embodiment, the fastener 10 is formed into the configuration of a continuous helix and may have a depth 16, a diameter 18 and a pitch 20 determined by the application. The continuous helix may be longitudinally collapsible and expandable. The cross-sectional profile of the continuous helix is substantially circular in the preferred embodiment but can be square,

rectangular or triangular. In a particular application such as mesh anchoring for hernia repair, the pre-formed pitch can be 1.27mm (.050 inches). However, the pre-formed pitch can vary from a minimum determined by the thickness of the material forming the helix to a maximum of approximately 3.0 times the coil diameter. In other embodiments, it is contemplated that the pitch 20 vary along the length of the fastener 10 so as to optimize the retaining force of the fastener 10. Moreover, since the continuous helical coil is preferably longitudinally collapsible and expandable, upon insertion into tissue, the final pitch 31 may be less than or greater than the pre-formed pitch. If the coil is made of rigid construction, as is also contemplated, the pitch would be made substantially fixed. The diameter in the preferred embodiment may be 5 mm; however, designs ranging from 1 mm and up are contemplated. In practice, the depth 16 of the fastener 10 must be selected so that the extent of fastener penetration into tissue is sufficient to hold the fastener 10 in place.

[0027] Moreover, distal end 22 of the fastener 10 is to be configured such that a gap 23 exists between the most distal coil 27 (or first coil) of the fastener 10 and its adjacent coil. As may be appreciated from the preferred embodiment of FIGS. 1B through 1E, as the fastener 10 is pressed against tissue 25, all of the coils substantially collapse except the most distal coil 27, leaving the gap 23 to determine the path the fastener 10 takes as it is rotated into the tissue 25 and more importantly, the extent of penetration 29 into the tissue 25 and final pitch 31 of the fastener 10 in tissue. Although FIG. 1B shows substantially all of the coils being collapsed, it is to be appreciated that, depending upon the applicator utilized to implant the fastener 10, fewer coils than all of the coils may be collapsed at any one time. It remains, however, that since the fastener 10 is longitudinally collapsible and expandable, it is the gap 23 that generally determines final pitch 31. Accordingly, the magnitude of the gap 23 can be varied, depending upon the application, to achieve the desired final pitch 31 and penetration 29 in tissue. Thus, the greater the gap 23, upon insertion of the fastener 10 in tissue, the greater the penetration 29 and final pitch 31 of the fastener 10 in tissue.

[0028] In the preferred embodiment, the distal end 22 of the helical fastener 10 terminates with a point 24. The point 24 may be sharp or blunt depending upon the tissue to which the fastener 10 will be affixed. Additionally, one or more barbs or a sharp point projecting in reverse direction to point 24 (not shown) can be added to fastener 10 near point 24 to enhance anchoring characteristics of the fastener. A proximal end 26 of the helical fastener 10 may comprise structure functioning to receive and transmit applied longitudinal forces. In the preferred embodiment, the most proximal coil is formed into a T-bar 33 that perpendicularly sections the diameter 18 of the fastener 10. In alternate embodiments, it is also contemplated that the most proximal coil section the diameter 18 non-perpendicularly or be formed into

a spiral 35 existing in a single plane (See FIG. 1F).

[0029] Concerning the material of the helical fastener 10, it is contemplated in the preferred embodiment that the fastener be made from semi-stiff implantable wire, such as titanium, wound into a helical shape. In alternate embodiments, the helical fastener 10 may comprise plastic or absorbable materials. Examples of materials that can be used in constructing the helical fastener 10 include titanium, titanium alloys, stainless steel, nickel, chrome alloys and any other biocompatible implantable metals. Other options for materials are liquid crystal polymers, HDPE, polyglycolic acid, and polyglycolid hydroxyacetic acid. Further, it may also be desirable to coat the fastener, or a portion thereof, with a biocompatible lubricious material that provides for easier delivery of the fastener into tissue.

[0030] In another embodiment of the surgical fastener, the fastener 110 is formed into the configuration of a double helix (See FIGS. 2-2C). By embodying a double helix, the fastener 110 has increased retentive strength as well as means to balance the fastener 110 as it is pressed into tissue. As with the helical fastener 10, the configuration of the double helical fastener 110, i.e., the pre-formed pitch and diameter, may be varied for a particular application and a barb may be employed to enhance anchoring in tissue. Moreover, the materials contemplated are the same as those for the helical fasteners. Further, the double helical fastener 110 is also longitudinally collapsible and expandable and its final pitch is dependent upon the gap 112 existing between the most distal coils 114, 115 of the fastener 110 and their adjacent coils.

[0031] Regarding the proximal 118 and distal 120 ends of the double helical fastener 110, they comprise structure to drive the fastener into tissue as well as tissue piercing structures. The proximal end 118 has a connector bar 122 sectioning the diameter of the fastener that connects one helical coil to another and functions to receive and transmit longitudinal forces. The distal end 120 terminates with two points 124, 125 for piercing and facilitating the implantation of the fastener 110 into tissue.

[0032] As may be appreciated by comparing FIGS. 2-2D with FIGS. 3-3D, it is contemplated that the double helical fastener 110 have a full turn design (FIGS. 2-2D) as well as a half turn design (FIGS. 3-3D). It is to be understood, however, that the designs having more than one turn and having other increments of turns are contemplated. It is the applicator that will determine the required number of turns for a specific fastener 110.

[0033] In yet another embodiment of the surgical fastener, as shown in FIG. 4, the double helical fastener 110 is provided with a pivot post 130 having a pointed terminal end 132. The pivot post 130 of this embodiment operates to provide the fastener 110 with a stabilizing element so that, as the fastener 110 is being turned, the helical coils cooperatively enter the tissue.

[0034] The applicator 12 (FIG. 5) comprises a proxi-

mal portion 28 having a handle 30 and an actuator 32 and a cooperating elongated distal portion or cannula 34 housing a plurality of fasteners. In general, through the manipulation of the actuator 32, the fasteners are ejected, one by one, out of a distal portion 34 and into body tissue. The applicator 12, hereinafter described in more detail, is equally proficient in driving each of the embodiments of fasteners set forth above into tissue.

[0035] In more detail (see FIGS. 6 and 6A), the distal portion 34 comprises an outer tube 36 housing a rotator 38, a lock/clip indicator 40 and a load spring 42. Extending longitudinally along the rotator 38 is a groove 44 which operates to receive the most proximal coil sectioning the fastener. Although FIG. 6 shows only a single fastener (having a single helical design) retained by the rotator 38, it is to be appreciated that the rotator 38 may receive a plurality of fasteners (having a single or double helical design), wherein each fastener has its last coil positioned within the rotator groove 44. Moreover, although not depicted in FIG. 3, it is also contemplated that rather than embodying a groove, the rotator 38 has a cross-sectional profile approximately a "D", wherein the flat portion operates to engage the coil sectioning the fasteners. Irrespective of the configuration of the rotator, however, the rotator is to embody structure functioning to engage a plurality of fasteners and to facilitate turning them into tissue.

[0036] It is also to be appreciated that load spring 42 applies a force through the lock clip indicator 40 to bias the plurality of fasteners distally. The lock clip/indicator 40 may comprise a simple washer sized and shaped to engage the fasteners and rotator 38 as well as to receive forces from the load spring 42. Additionally, lock/clip indicator 40 serves as a jam stop to prevent further actuation by rotator 38 upon discharge of all fasteners by mating with, or abutting against, structure comprising the terminal end 50 and preventing further rotation. Lock/indicator 40 can be made of a color (or shape) to serve as an empty indicator notifying the user that no more fasteners are available. Other embodiments of the indicator 40 may be utilized as long as they function to transmit forces to bias the fasteners distally. The load spring 42 is to be retained within the outer tube 36 and to have physical characteristics such that sufficient forces may be applied through a front end 43 to a last remaining fastener contained within the applicator 12. A back end (not shown) of the load spring 42 may be placed against any stationary structure within the outer tube 36, thereby providing a foundation against which the spring 42 may be compressed. In a preferred embodiment, the load spring 42 extends substantially the length of the distal portion 34.

[0037] In the preferred embodiment (FIGS. 7 and 7A), the outer tube 36 is configured with a thread form 201 comprising an interlock spring 203 fixedly retained within the outer tube 36 and extending substantially the length thereof. The interlock spring 203 may be fixedly retained within the outer tube 36 by ensuring a tight in-

interference between the parts or the interlock spring may be spot welded or equivalently bonded within the outer tube. The thread form 201 operates to guide the fasteners through the distal portion 34 and to eject them from the applicator 12.

[0038] In another embodiment of the applicator 12 (FIGS. 8 and 8A), attached at a terminal end 46 of the distal portion 34 may be a nose piece 48. The nose piece 48 may further comprise a protrusion 50 extending perpendicularly and towards a longitudinal axis 52 of the distal portion 34. This nose piece protrusion 50 also functions to engage the surgical fasteners and to force them from the terminal end 46 of the distal portion 34 as well as engaging lock/clip indicator 40 as described above.

[0039] In other embodiments of the applicator 12, the distal portion embodies other structure or thread forms functioning to engage the surgical fasteners and guide them out of the applicator and into tissue (See FIGS. 9-14). In FIGS. 9 and 9A, the outer tube 36 is rolled at its terminal end 46 and a 180° portion of the rolled terminal end is cut away. The remaining rolled portion engages the fastener while the portion cut away provides an exit for the fasteners. The embodiment depicted in FIGS. 10 and 10A is similar to that of FIGS. 9 and 9A, the difference being that instead of removing a portion of the rolled terminal end 46, it is stamped or deformed to thereby provide an exit. FIGS. 11 and 11A show yet another embodiment, wherein two longitudinally spaced apart stabilizing points 301, 302 are formed 180° from each other within the outer tube. These stabilizing points also operate to engage the fastener and guide it into tissue. Turning to FIGS. 12, 12A, 13 and 14, they each comprise a terminal end 46 formed with threads which operate to engage and eject a fastener. In FIGS. 12 and 12A are depicted threads machined or formed solely within the inside of the outer tube. FIG. 13 shows an internally threaded sleeve attached to the outside of the terminal end 46 of the outer tube 36. FIG. 14 illustrates an applicator 12 provided with a terminal end 46 deformed so as to have internal and external threaded structures. Irrespective of the design chosen for the terminal end of the applicator, however, each of the designs are effective with a relatively small overall outer diameter, i.e., on the order of 5mm.

[0040] In order to eject surgical fasteners from the distal portion 34, the actuator 32 functions to turn the rotator 38. As the rotator turns, the distal end 22 of a fastener is threaded out of the terminal end 46 of the applicator 12 (see FIG. 5).

[0041] In the preferred embodiment of the proximal portion 28 of the applicator 12 (See FIG. 5), a lever 54 is pivotally connected about a midpoint 56 to the handle 30. A first end 58 of the lever 54 is to be configured for gripping by hand. A second end 60 of the lever is to be adapted to pivotally engage a nut driver 62.

[0042] The nut driver 62 of the applicator 12 travels upon a high helix lead screw 64 which is rotatably

mounted within the proximal portion 28. In the preferred embodiment, a longitudinal axis of the high helix lead screw 64 is coaxial with the longitudinal axis 52 extending through the distal portion 34 of the applicator 12. Upon manipulation of the lever 54, the nut driver 62 travels along the lead screw 64 causing it to rotate through a connection of the lead screw 64 to the rotator 38, the action of the lead screw causes the rotator to rotate. The lead screw 64 may be connected to the rotator 38 by any conventional means. For instance, the lead screw 64 can have an internal bore receiving and engaging an end of the rotator 38. Further, the length of travel of the nut driver 62 along the lead screw 64 is chosen such that it causes the rotator to rotate a predetermined number of times so that a single helical fastener 10 is ejected from the applicator 12.

[0043] Additionally, in the preferred embodiment, the lever further comprises a midsection extension 66. Pivotally attached to the midsection extension 66 of the lever 54 is contemplated to be a spring loaded pawl 68 adapted to releasably engage gear teeth 70 formed in the interior of the handle 30. Spring loaded pawl 68 is configured to prohibit the lever 54 from backstroking until it has been completely depressed. Upon complete depression of the lever 54, the pawl 68 clears the gear teeth 70 and the spring biasing the pawl 68 rotates the pawl 68 away from the teeth 70, thereby allowing the lever 54 to return to its undepressed condition.

[0044] In operation, upon complete depression of the lever 54, the nut driver 62 travels a pre-determined distance along the lead screw 64, causing the rotator 38 to rotate a pre-determined number of revolutions corresponding to a number of turns of a particular helical fastener 10. As the rotator 38 rotates, the fasteners retained by the rotator also rotate and the coils of the most distal fastener are threaded out of the terminal end 46 of the applicator 12 and into tissue. Moreover, where the lever 54 is only partially depressed, the spring loaded pawl 68 operates to hold the lever 54 stationary and will continue to function to hold the lever 54 stationary until the lever 54 has been completely depressed. In this way, the delivery of fasteners into body tissue is controlled so that only a single fastener may be completely ejected out of the applicator 12 and pressed into body tissue at a time.

[0045] In the preferred embodiment, the proximal portion 28 is fabricated to have a reusable handle that can be re-sterilized, and the distal portion is made disposable. Thus, upon discharge of all the fasteners 10 from distal portion 34, the distal portion would be discarded and replaced. The handle could be reused up to a limited number of procedures.

[0046] In another embodiment of the proximal portion 328, of the applicator 312 (FIG. 15), a lever 354 is pivotally connected at a first end 355 to the handle 330 and biased to its undepressed position by a spring 357. The mid-section 358 of the lower 354 is configured for gripping by hand. A second end 360 of the lever is to be

adapted to pivotally engage a nut drive 362.

[0047] The nut driver 362 of the applicator 312 travels along a high helix lead screw 364 which is rotatably mounted within the proximal portion 328. Upon manipulation of the lever 354, the nut driver travels along the lead screw 364 causing it to rotate and, through a clutch assembly or a releasable connection of the lead screw 364 to the rotator 38, the action of the lead screw causes the rotator to rotate.

[0048] Further, the lever 354, has a mid-section extension 366 that cooperates with a spring biased latch pawl mechanism 368 fixed to the handle adapted to releasably engage teeth 370 formed on the mid-section extension 366. The spring biased latch pawl is configured to prohibit the lever 354 from backstroking until it has been completely depressed. Upon complete depression of the lever 354, the latch pawl 368 clears the mid-section teeth 370 and the spring biased latch pawl 368 rotates away from the teeth, thereby allowing the lever 354 to return to its undepressed condition.

[0049] As stated, there is a releasable connection between the lead screw 364 and the rotator. The releasable connection provides the applicator with means to disengage the distal portion of the applicator from the proximal portion. In this way, the proximal portion can be re-used with various different designs of the proximal portion. Further, while the lever 354 is being depressed, the clutch assembly or releasable connection functions to transfer the rotation of the lead screw 364 to the rotator 38, thereby causing the rotator to rotate. Additionally, upon complete depression of the lever, the clutch assembly operates to allow relative motion of the lead screw 364 and the rotator.

[0050] One such releasable connection contemplated is a conventional ratchet mechanism. As shown in FIGS. 16-16D, the distal end 370 of the lead screw 364 has a connecting surface 372 equipped with leaf springs 374, 376 each having an engaging face 377 and an internal bore 378 existing coaxially with a longitudinal axis of the lead screw. The proximal end 380 of the rotator 38 has a cooperating connecting surface 382 having ridges 384 for releasable engagement with the leaf springs 374, 376 and an extension 386 adapted to fit within the internal bore of the lead screw connecting surface. As may be appreciated from the FIGS., as the lead screw turns so that the ridges 384 contact the engaging faces 377 of the leaf springs 374, 376, the rotation of the lead screw 364 will cause the rotator 38 to likewise rotate. Where the lead screw is turned in the opposite direction, the ridges 384 will not engage the engaging face of the leaf springs and the motion of the lead screw 384 will not be transferred to the rotator 38.

[0051] In this embodiment, upon complete depression of the lever 354, the nut driver 362 travels a predetermined distance along the lead screw 364, causing the rotator 38 to rotate a pre-determined number of revolutions. As the rotator 38 rotates, the fasteners retained by the rotator also rotate and the coils of the most distal

fasteners are threaded out of the applicator and into the tissue. At this point, the latch pawl mechanism 368 disengages from the teeth 370 and the lever 354 is returned to its undepressed position by spring 357. As with the previous embodiment of the proximal portion 28, the proximal portion of this embodiment functions to allow only a single fastener to be completely ejected from the applicator and be pressed into body tissue at a time.

[0052] In other embodiments, means to cause the rotator to rotate may comprise a single knob connected to a rotator which can be turned by hand. Additionally, the revolving means may include a rack and gear structure or a set of beveled gears. Further, instead of comprising a groove, the rotator may be internally threaded, where in the threaded portions function to house as well as advance the helical fasteners 10. Irrespective of the means or structure employed, however, it is contemplated that the number of revolutions of the rotator be set to a predetermined parameter so that the delivery of helical fasteners to tissue may be controlled.

[0053] From the foregoing, it will be appreciated that the helical fastener and applicator of the present invention function to securely attach a fastener with high retentive surface area to tissue from one direction through the utilization of an applicator having a simple design. It is also to be appreciated that the present invention may be utilized in a number of applications including ligating tissue, hernia mesh repair, bladder neck suspension, and in conjunction with implant drug delivery systems or procedures involving positioning of surgical or implantable devices in patient.

[0054] While several particular forms of the invention have been illustrated and described, it will also be apparent that various modifications can be made without departing from the scope of the invention.

Claims

1. A system for ligating tissue or attaching an implantable device, the system comprising a plurality of continuous helical coils (10) each having a distal end (22), a proximal end (26) and a first helical coil section at said distal end (22), said distal end (22) being configured to pierce tissue and said proximal end (26) being configured to receive and translate rotational forces; and
an applicator (12) for applying rotational forces to said proximal end (26) of said continuous helical coils (10), said applicator (12) including ratcheting means (68,70) so that only a single continuous helical coil (10) may be completely ejected out of the applicator (12) at a time.
2. The system of claim 1, wherein said applicator (12) includes a distal portion (34) and a proximal portion (28), said distal portion (34) being configured to retain said plurality of continuous helical coils (10) and

to sequentially deploy each said continuous helical coil (10) into tissue.

3. The system of claim 1, or claim 2 wherein said continuous helical coils (10) are longitudinally collapsible and expandable.
4. The system of any preceding claim, wherein said distal ends (22) of said continuous helical coils (10) are configured with a point (24).
5. The system of claim 4, wherein a gap (23) is defined between said point (24) of said first helical coil section and an adjacent coil section, the magnitude of said gap being variable to achieve a desired depth of penetration and pitch of said continuous helical coils (10) in tissue and retentive strength of said continuous helical coils (10) in tissue.
6. The system of any preceding claim, wherein said continuous helical coils (10) have a stiffness such that a pitch (20) between coils can be varied by said applicator (12).
7. The system of any preceding claim, wherein said continuous helical coils (10) include at least one barb projecting in a reverse direction and positioned proximate to said distal end (22).
8. The system of any preceding claim, wherein said proximal end (26) of said continuous helical coils (10) are configured into a T-bar (33) that extends along a line sectioning a cross-sectional profile of said continuous helical coil (10).
9. The system of any of claims 1 to 7, wherein said continuous helical coils comprises a continuous double helix having a distal end (120) terminating with a first point (124) and a second point (125), a proximal end (118) including a connecting bar (122) and a first helical coil section (114) and a second helical coil section (115), said first and second helical coil sections (114,115) being adjacent said distal end (120) and being associated with said first and second points (124,125) and defining a gap (112) therebetween, and wherein the applicator (12) is adapted to be capable of applying rotational forces to said connecting bar.
10. The system of claim 9, wherein said continuous double helical coils includes a pivot post (130) extending from said connecting bar (122) and toward said distal end (120), said pivot post (130) having a pointed terminal end (132).

Patentansprüche

1. System zum Verbinden von Gewebe oder Anbringen einer implantierbaren Vorrichtung, wobei das System eine Mehrzahl kontinuierlicher Schraubwendel (10) aufweist, die jeweils ein distales Ende (22), ein proximales Ende (26) und einen ersten Schraubwendelabschnitt an dem distalen Ende (22) aufweisen, wobei das distale Ende (22) zum Durchstechen von Gewebe konfiguriert ist und das proximale Ende (26) zur Aufnahme und Übertragung von Drehkräften konfiguriert ist; und einen Applikator (12) zum Anlegen von Drehkräften an das proximale Ende (26) der kontinuierlichen Schraubwendel (10), wobei der Applikator (12) ein Ratschenmittel (68, 70) aufweist, sodass auf einmal nur ein einzelner kontinuierlicher Schraubwendel (10) vollständig aus dem Applikator (12) ausgegeben werden kann.
2. System nach Anspruch 1, worin der Applikator (12) einen distalen Abschnitt (34) und einen proximalen Abschnitt (28) enthält, wobei der distale Abschnitt (34) konfiguriert ist, um die Mehrzahl kontinuierlicher Schraubwendel (10) zu halten und um sequenziell jeden kontinuierlichen Schraubwendel (10) in Gewebe einzusetzen.
3. System nach Anspruch 1 oder Anspruch 2, worin die kontinuierlichen Schraubwendel (10) längs kollabierbar und expandierbar sind.
4. System nach einem der vorhergehenden Ansprüche, worin die distalen Enden (22) der kontinuierlichen Schraubwendel (10) mit einer Spitze (24) konfiguriert sind.
5. System nach Anspruch 4, worin zwischen der Spitze (24) des ersten Schraubwendelabschnitts und einem benachbarten Wendelabschnitt eine Lücke (23) definiert ist, wobei die Größe der Lücke variabel ist, um eine gewünschte Eindringtiefe und Steigung der kontinuierlichen Schraubwendel (10) in das Gewebe und eine Retentionsfestigkeit der kontinuierlichen Schraubwendel (10) in dem Gewebe zu erreichen.
6. System nach einem der vorhergehenden Ansprüche, worin die kontinuierlichen Schraubwendel (10) eine derartige Steifigkeit haben, dass eine Steigung (20) zwischen Wendeln durch den Applikator (12) variiert werden kann.
7. System nach einem der vorhergehenden Ansprüche, worin die kontinuierlichen Schraubwendel (10) zumindest einen Haken aufweisen, der in Rückwärtsrichtung vorsteht und nahe dem distalen Ende (22) angeordnet ist.

8. System nach einem der vorhergehenden Ansprüche, worin das proximale Ende (26) der kontinuierlichen Schraubwendel (10) zu einer Querstange (33) konfiguriert ist, die sich längs einer Linie erstreckt, die ein Querschnittsprofil des kontinuierlichen Schraubwendels (10) schneidet.
9. System nach einem der Ansprüche 1 bis 7, worin der kontinuierliche Schraubwendel eine kontinuierliche Doppelhelix aufweist, die ein distales Ende (120), das an einer ersten Spitze (124) und einer zweiten Spitze (125) endet, ein proximales Ende (118), das eine Verbindungsstange (122) enthält, sowie einen ersten Schraubenwendelabschnitt (114) und einen zweiten Schraubenwendelabschnitt (115) aufweist, wobei die ersten und zweiten Schraubenwendelabschnitte (114, 115) dem distalen Ende (120) benachbart sind und den ersten und zweiten Spitzen (124, 125) zugeordnet sind und dazwischen eine Lücke (112) definieren, und worin der Applikator (12) dazu ausgelegt ist, auf die Verbindungsstange Drehkräfte auszuüben.
10. System nach Anspruch 9, worin der kontinuierliche Doppelhelixwendel einen Schwenkposten (130) enthält, der von der Verbindungsstange (122) und zu dem distalen Ende (120) hin absteht, wobei der Schwenkposten (130) ein zugespitztes Schlussende (132) aufweist.

Revendications

1. Système pour ligaturer des tissus ou attacher un dispositif implantable, le système comportant une pluralité de spirales hélicoïdales continues (10) ayant chacune une extrémité distale (22), une extrémité proximale (26) et une première section de spirale hélicoïdale à ladite extrémité distale (22), ladite extrémité distale (22) étant configurée de façon à percer un tissu et ladite extrémité proximale (26) étant configurée de façon à recevoir et translater des forces de rotation ; et
- un applicateur (12) destiné à appliquer des forces de rotation à ladite extrémité proximale (26) desdites spirales hélicoïdales continues (10), ledit applicateur (12) comprenant des moyens d'encastrement (68, 70) afin qu'une seule spirale hélicoïdale continue (10) à la fois puisse être totalement éjectée de l'applicateur (12).
2. Système selon la revendication 1, dans lequel ledit applicateur (12) comprend une partie distale (34) et une partie proximale (28), ladite partie distale (34) étant configurée de façon à retenir ladite pluralité de spirales hélicoïdales continues (10) et à déployer séquentiellement chaque spirale hélicoïdale continue (10) dans le tissu.

3. Système selon la revendication 1 ou la revendication 2, dans lequel lesdites spirales hélicoïdales continues (10) peuvent être resserrées et expansées longitudinalement.
4. Système selon l'une quelconque des revendications précédentes, dans lequel lesdites extrémités distales (22) desdites spirales hélicoïdales continues (10) sont configurées en une pointe (24).
5. Système selon la revendication 4, dans lequel un espace (23) est défini entre ladite pointe (24) de ladite première section de spirale hélicoïdale et une section de spirale adjacente, la grandeur dudit espace étant variable pour obtenir une profondeur souhaitée de pénétration et un pas desdites spirales hélicoïdales continues (10) dans le tissu et une force de retenue desdites spirales hélicoïdales continues (10) dans le tissu.
6. Système selon l'une quelconque des revendications précédentes, dans lequel lesdites spirales hélicoïdales continues (10) ont une raideur telle que ledit applicateur (12) puisse faire varier un pas (20) entre les spires.
7. Système selon l'une quelconque des revendications précédentes, dans lequel lesdites spirales hélicoïdales continues (10) comprennent au moins un arillon faisant saillie dans une direction opposée et positionné à proximité de ladite extrémité distale (22).

8. Système selon l'une quelconque des revendications précédentes, dans lequel ladite extrémité proximale (26) desdites spirales hélicoïdales continues (10) est configurée en une barre en T (33) qui s'étend suivant une ligne coupant un profil en section transversale de ladite spirale hélicoïdale continue (10).
9. Système selon l'une quelconque des revendications 1 à 7, dans lequel lesdites spirales hélicoïdales continues comprennent une hélice double continue ayant une extrémité distale (120) se terminant par une première pointe (124) et une seconde pointe (125), une extrémité proximale (118) comprenant une barre de liaison (122) et une première section (114) de spirale hélicoïdale et une seconde section (115) de spirale hélicoïdale, lesdites première et seconde sections (114, 115) de spirale hélicoïdale étant adjacentes à ladite extrémité distale (120) et étant associées auxdites première et seconde pointes (124, 125) et définissant entre elles un espace (112), et dans lequel l'applicateur (12) est conçu pour pouvoir appliquer des forces de rotation à ladite barre de liaison.

10. Système selon la revendication 9, dans lequel les dites spirales hélicoïdales doubles continues comprennent une colonnette (130) formant pivot s'étendant depuis ladite barre de liaison (122) et vers ladite extrémité distale (120), ladite colonnette (130) formant pivot ayant une extrémité terminale pointue (132).

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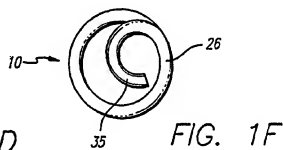
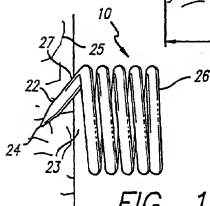
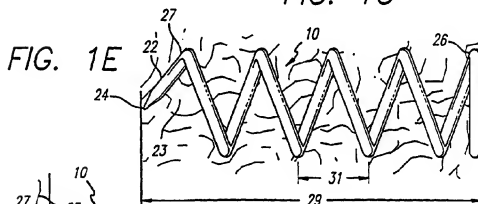
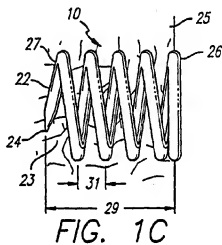
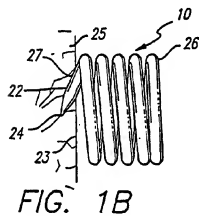
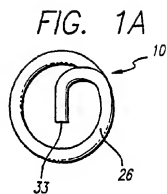
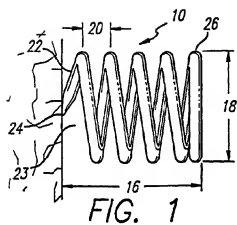
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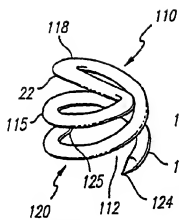


FIG. 2

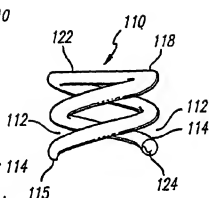


FIG. 2A

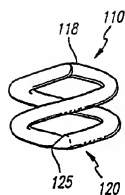


FIG. 2B

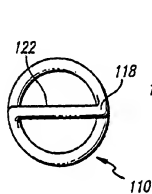


FIG. 2C

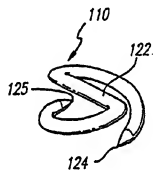


FIG. 3

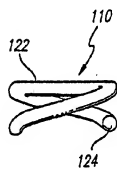


FIG. 3A

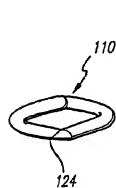


FIG. 3B

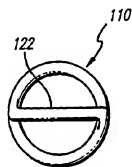


FIG. 3C



FIG. 4

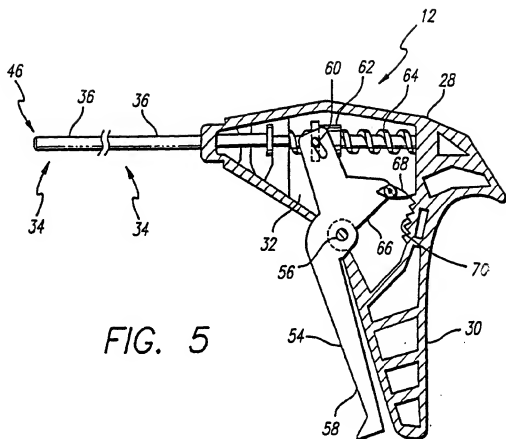


FIG. 5

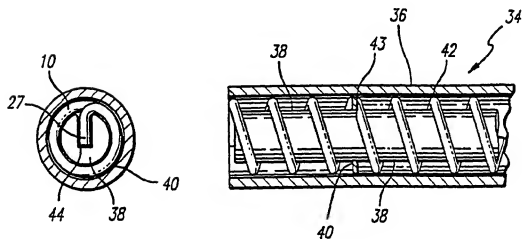


FIG. 6A

FIG. 6

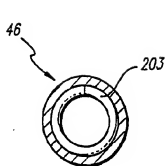


FIG. 7A

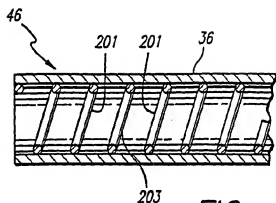


FIG. 7

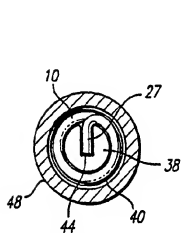


FIG. 8A

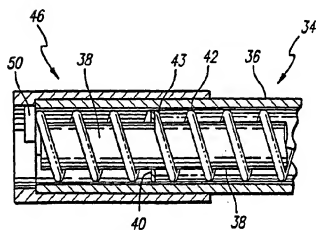


FIG. 8

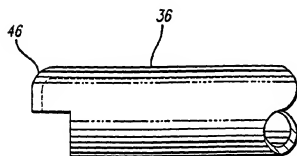


FIG. 9



FIG. 9A

FIG. 10

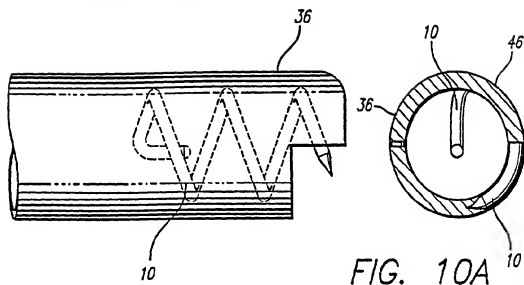


FIG. 10A

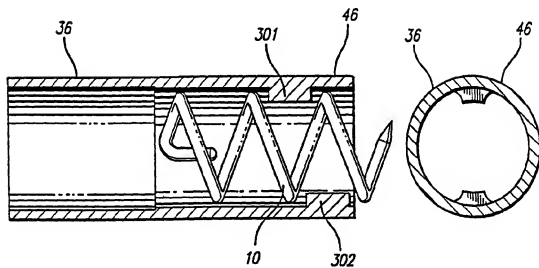


FIG. 11

FIG. 11A

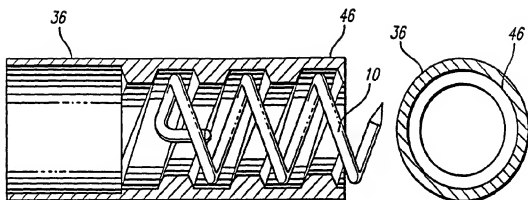


FIG. 12

FIG. 12A

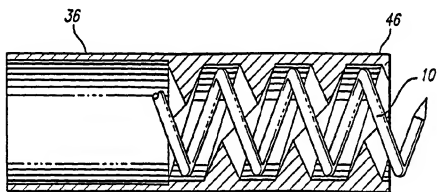


FIG. 13

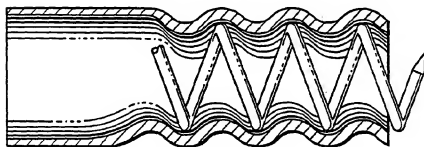
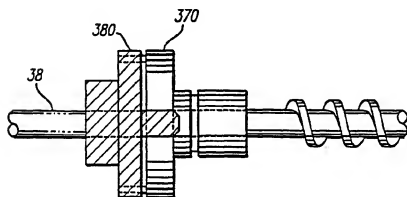
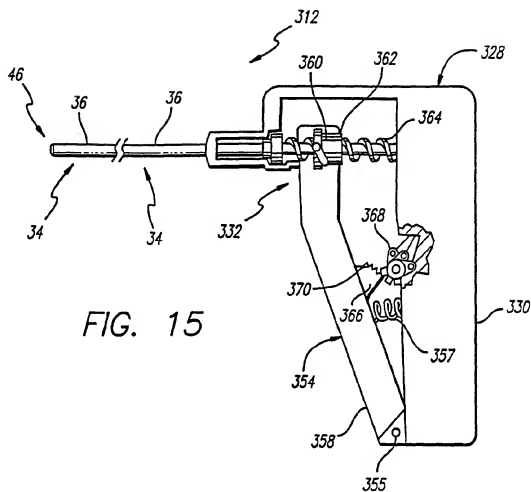


FIG. 14



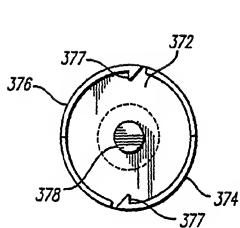


FIG. 16A

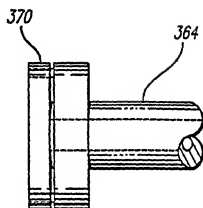


FIG. 16B

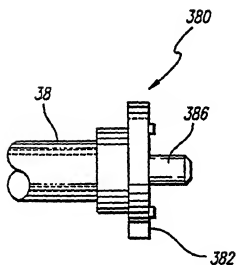


FIG. 16C

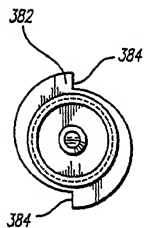


FIG. 16D



(12)

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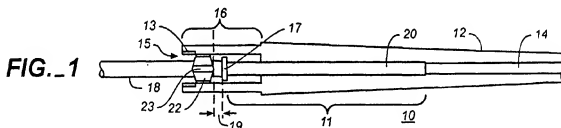
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(54) Controlled deployment delivery system

(57) A controlled stent-graft deployment delivery system (10 50 or 900) includes a stent-graft (30 or 63), a retractable primary sheath (40) containing the stent-graft in a first constrained diameter configuration, an outer tube (18) within the retractable primary sheath and within the stent-graft, and an inner tube (20) within the outer tube, where the inner tube and the outer tube both axially move relative to the retractable primary sheath

and to each other. The system further includes a cap (15) coupled to a distal end of the inner tube and configured to retain at least a portion of a proximal area of the stent-graft in a radially compressed configuration. A distal assembly (100) provides controlled relative axial movement between the outer tube and the inner tube enabling the release of the proximal end (65, 67, 68, and 69) of the stent-graft from the cap and from the radially compressed configuration.



Description

[0001] This application is a continuation in part of provisional application serial number 60/387,278 filed on 06/07/2002 and hereby claims priority therefrom.

[0002] This invention relates generally to medical devices and procedures, and more particularly to a method and system of deploying a stent-graft in a vascular system.

[0003] Prostheses for implantation in blood vessels or other similar organs of the living body are, in general, well known in the medical art. For example, prosthetic vascular grafts formed of biocompatible materials (e.g., Dacron or expanded, porous polytetrafluoroethylene (PTFE) tubing) have been employed to replace or bypass damaged or occluded natural blood vessels. A graft material supported by framework is known as a stent-graft or endoluminal graft. In general, the use of stent-grafts for treatment or isolation of vascular aneurysms and vessel walls which have been thinned or thickened by disease (endoluminal repair or exclusion) are well known. Many stent-grafts, are "self-expanding", i.e., inserted into the vascular system in a compressed or contracted state, and permitted to expand upon removal of a restraint. Self-expanding stent-grafts typically employ a wire or tube configured (e.g. bent or cut) to provide an outward radial force and employ a suitable elastic material such as stainless steel or Nitinol (nickel-titanium). Nitinol may additionally employ shape memory properties. The self-expanding stent-graft is typically configured in a tubular shape of a slightly greater diameter than the diameter of the blood vessel in which the stent-graft is intended to be used. In general, rather than inserting in a traumatic and invasive manner, stents and stent-grafts are preferably deployed through a less invasive intraluminal delivery, i.e., cutting through the skin to access a lumen or vasculature or percutaneously via successive dilatation, at a convenient (and less traumatic) entry point, and routing the stent-graft through the lumen to the site where the prosthesis is to be deployed.

[0004] Intraluminal deployment in one example is effected using a delivery catheter with coaxial inner (plunger) and outer (sheath) tubes arranged for relative axial movement. The stent graft is compressed and disposed within the distal end of an outer catheter tube in front of an inner tube. The catheter is then maneuvered, typically routed through a lumen (e.g., vessel), until the end of the catheter (and the stent-graft) is positioned in the vicinity of the intended treatment site. The inner tube is then held stationary while the outer tube of the delivery catheter is withdrawn. The inner tube prevents the stent-graft from moving back as the outer tube is withdrawn. As the outer tube is withdrawn, the stent graft is gradually exposed from a proximal end to a distal end of the stent graft, the exposed portion of the stent-graft radially expands so that at least a portion of the expanded portion is in substantially conforming surface contact with

a portion of the interior of the lumen e.g., blood vessel wall. The proximal end of the stent-graft is the end closest to the heart whereas the distal end is the end furthest away from the heart during deployment. In contrast and of note, the distal end of the catheter is usually identified to the end that is farthest from the operator while the proximal end of the catheter is the end nearest the operator. Depending on the access location the stent graft and delivery system description may be consistent or opposite. Logic should prevail to understand the description of an actual systems below.

[0005] Many self expanding stent-graft deployment systems are configured to have the proximal end of the stent-graft deploy as the outer tube or sheath is pulled back. The proximal end of the stent-graft is typically designed to fixate and seal the stent graft to the wall of the vessel during deployment. Such a configuration leaves little room for error in placement since re-positioning the stent-graft after initial deployment, except for a minimal pull down retraction, is usually difficult if possible at all. Deploying the proximal end of the stent-graft first makes accurate pre-deployment positioning of the stent-graft critical

[0006] One attempt to overcome this problem by W. L. Gore utilized a flexible jacket that deploys the stent-graft with a ripcord that opens the jacket along the longitudinal axis of the flexible jacket, e.g., U.S. Patent 6,315,792. Unfortunately, this method introduced a separate non-integrated sheath into the system into the femoral artery and further failed to provide the desired control during deployment. Other stent-graft delivery systems have also attempted to confine the proximal end of the stent-graft, but generally fail to provide adequate control in manipulating the stent-graft positioning in both the initial deployment of the stent graft and the re-deployment of the stent-graft (once the stent-graft has been partially deployed). Another problem encountered with existing systems, particularly with systems that have a distal end of a stent-graft fixed during deployment (or during the uncovering of a sheath) is the frictional forces that can cause the stent-graft to axially compress or bunch up as the sheath is retracted. This bunching increases the density of the stent-graft within the sheath and can further increase the frictional drag experienced during deployment. Thus, a need exists for a method and deployment system that enables partial deployment of a stent-graft while constraining a proximal end of the stent-graft, provides adequate control to enable re-deployment of the stent-graft in various dimensions and further reduces deployment forces during advancement of the stent-graft.

[0007] The present invention intends to overcome at least some of the above problems. The object is solved by the controlled stent-graft deployment delivery system according to independent claims 1, 7, 19 and 22 and the method for controlled deployment of a stent-graft according to independent claim 16.

[0008] Further advantages, features, aspects and de-

tails of the invention are evident from the dependent claims, the description and the accompanying drawings.

[0009] The present invention generally relates to medical devices and processes. In particular it relates to a method and system of deploying a stent-graft in a vascular system. More specifically, the present invention relates to controlled stent-graft deployment delivery system.

[0010] In a first aspect according to the present invention, a controlled stent-graft deployment delivery system includes a stent-graft, a retractable primary sheath containing the stent-graft in a first constrained diameter configuration, an outer tube within the retractable primary sheath and within the stent-graft, and an inner tube within the outer tube, where the inner tube and the outer tube both move axially relative to the retractable primary sheath and to each other. The system further includes a cap coupled to a distal end of the inner tube and configured to retain at least a portion of a proximal end of the stent-graft in a radially compressed configuration. A controlled relative axial movement between the outer tube and the inner tube releases the proximal end of the stent-graft from the cap and from the radially compressed configuration.

[0011] Preferably, the controlled stent-graft deployment delivery system can have a cap formed from a shroud portion in a flexible tapered tip coupled at the distal end of the inner tube and further include a threaded collar coupled to the inner tube and a mating threaded shaft coupled to the outer tube that enables the relative axial movement between the inner tube and the outer tube for controlled deployment of the stent-graft. The system can further include a proximal lock attached to the outer tube, wherein the stent-graft has a zig zag shaped radially expanding proximal spring at the proximal end of the stent-graft. The apices of the spring at one end remain latched onto the proximal lock in the radially compressed configuration while the spring's end remains captured within the cap. The proximal lock can further include a plurality of ribs or splines for retaining the plurality of apices of the proximal spring of the stent-graft.

[0012] In a second aspect according to the present invention, a controlled stent-graft deployment delivery system includes a retractable primary sheath, an outer tube within the retractable primary sheath, an inner tube within the outer tube that can move axially relative to the outer tube, and a cap coupled to a distal end of the inner tube. The system can further include a retention mechanism attached to the outer tube for retaining a proximal end of a stent-graft in a constrained diameter configuration while remaining within the cap while still enabling axial and radial movement of the stent-graft.

[0013] In a third aspect according to the present invention, a method for controlled deployment of a stent-graft includes the steps of constraining a proximal end of a stent-graft radially under a cap while partially deploying a remaining portion of the stent-graft, evaluating

and adjusting as necessary at least one of the axial and radial positions of the stent-graft after the partial deployment of the remaining portion, and releasing the proximal area of the stent-graft by minimal controlled coaxial movement between the cap and a tube retaining the stent-graft within the cap.

[0014] The invention is also directed to apparatus for carrying out the disclosed methods and including apparatus parts for performing each described method steps. Furthermore, the invention is also directed to methods by which the described apparatus operates. It includes method steps for carrying out every function of the apparatus.

[0015] The invention will be better understood by reference to the following description of embodiments of the invention taken in conjunction with the accompanying drawings, wherein

[0016] FIG. 1 is a partial cross sectional view of a stent-graft deployment delivery system without a stent-graft and outer sheath in accordance with the present invention.

[0017] FIG. 2 is a close up schematic cross sectional view of the deployment delivery system of FIG. 1 having a stent-graft loaded within an outer sheath.

[0018] FIG. 3 is a close up schematic cross sectional view of the deployment delivery system of FIG. 2 showing partial deployment of the proximal portion of the stent graft as proximal end of the stent-graft remains constrained while the distal end of the stent graft remains loaded in its outer sheath.

[0019] FIG. 3A is a partial cross sectional view of the stent graft shown in Fig. 3, but without the distal end of the catheter and retaining shaft which is shown in Figure 3.

[0020] FIG. 3B is an oblique view of a stent of the type to be deployed in a delivery mechanism as shown in Fig. 3.

[0021] FIG. 4 is a partial cross sectional view of the stent-graft deployment delivery system of FIG. 1 with the proximal end of the stent-graft deployed.

[0022] FIG. 5 is a partial cross sectional view of another stent-graft deployment delivery system with a proximal spring crowns constrained within a cap.

[0023] FIG. 5A shows a revised position of the end of the stent graft delivery system shown in FIG 5 where the proximal lock catch is shown engaged with the backplate so that premature release does not occur during shipping and delivery prior to an operator's positioning the stent graft at its intended delivery location.

[0024] FIG. 6 illustrates the stent-graft deployment delivery system of FIG. 5 with the plurality of proximal spring crowns released from under the cap.

[0025] FIG. 7 illustrates a proximal lock sub-assembly that can be used with a stent-graft deployment delivery system.

[0026] FIG. 8 is a cross sectional schematic diagram illustrating a spinning collar actuation assembly used in conjunction with a stent-graft deployment delivery sys-

tem.

[0027] FIG. 9 is a schematic diagram illustrating a stent-graft deployment delivery system in accordance with the present invention.

[0028] FIGS. 1-4 show portions of a stent-graft deployment delivery system 10. The vertical dashed line provides a reference line to provide correlation between the FIGs. to a common location related to the position of the end spring of the stent graft as elements of the delivery system are manipulated to at first partially deploy and then fully deploy the proximal end of the stent graft 30.

[0029] FIG. 1 illustrates the distal tapered tip portion of the delivery system 10 alone without a stent-graft while FIGS. 2-4 show close up views of the deployment delivery system tip portion loaded with a stent-graft 30, with progressive figures showing deployment from within a retractable primary sheath 40. This system could also deploy a stent alone or some other form of endoprosthesis. The subsequent use of "stent-graft" herein should be understood to include other forms of endoprosthesis.

[0030] A configuration of the stent-graft deployment system 10 includes a tapered tip 12 that is flexible and able to provide trackability in tight and tortuous vessels. The tapered tip 12 can include a lumen 14 allowing for passage of a guidewire for example. Other tip shapes such as bullet-shaped tips could also be used.

[0031] The retractable primary sheath 40 (preferably made of a semi-rigid material such as PTFE) in an un-retracted position contains the stent-graft 30 in a first constrained diameter configuration as shown in FIG. 2. An outer tube 18 is located within the retractable primary sheath 40 and within the stent-graft 30 as shown in FIGs 1 and 4. An inner tube 20 within the outer tube 18 serves as a guidewire lumen. The inner tube 20 and the outer tube 18 can move along the longitudinal axis relative to each other and can also move along the longitudinal axis relative to the retractable primary sheath. A cap 15 is coupled to a distal area or end portion 11 of the inner tube 20 and is further configured to retain at least a portion of a proximal end of the stent-graft 30 in a radially compressed configuration. Actuating members at the operator's end of the catheter create a relative force in an axial direction to provide a controlled relative axial movement between the outer tube 18 and the inner tube 20 to precisely control the release of the proximal end of the stent-graft (such as proximal springs) from the cap and from the radially compressed configuration.

[0032] FIG. 2 illustrates the system 10 with the stent-graft 30 loaded in the delivery system. The stent graft is located within the retractable primary sheath 40 in a pre-deployment un-retracted position.

[0033] FIG. 3 illustrates the system 10 with the sheath 40 partially retracted. The proximal end (tip) of the stent-graft 30 is constrained while a proximal portion of the stent-graft 30 (that is now exposed due to the partial retraction of the sheath 40) between the end of the sheath

40 and the constrained proximal end (tip) is partially deployed, which allows longitudinal repositioning of the stent graft before releasing the proximal end (the release of the proximal end of the stent graft prevents repositioning of the stent graft in a direction toward the proximal end of the stent graft, while depending on the degree of expansion and contact between the stent graft and the wall of the vessel in which the stent graft is being deployed, some pull down (movement toward the distal end of the stent graft) of the stent graft is possible.

[0034] FIG. 3A is a selected partial schematically consistent view of the phase of stent graft deployment shown in Fig. 3, where the distal end of the catheter and retaining shaft are not included, for clarity. In FIG 3A the sheath appears to be farther retracted, and the size proportion, while not fully consistent with FIG 3, is nevertheless schematically consistent. In this figure it can be seen that deployment of the stent graft can be halted and the stent graft repositioned, rotated or moved in either direction axially without great a substantial risk of damaging the walls of the vessel.

[0035] In FIG. 4 the proximal end of the stent-graft 30 is shown as having been deployed by the controlled relative axial movement between the inner tube 20 and the outer tube 18. In particular, as shown in FIGs. 1-4, an end cap 15 containing the proximal apices of the end spring of the stent graft can be formed from a shroud portion of the tapered tip 12 which is coupled to the distal end of the outer tube 18. Within the shroud portion (formed by tubular body portion 16 of the tapered tip 12) preferably resides a back plate 17 coupled to a distal portion or end of the outer tube 18 that serves as a proximal stop for the stent-graft 30. The tubular body portion 16 of the shroud portion may also include a support (reinforcing) ring 13 near the proximal end of the tapered tip 12 to provide additional rigidity to the cap and prevents the cap shroud portion 16, which is preferably made of a plastic material from stretching (or distorting) in diameter. This configuration thereby prevents premature release of the of the proximal end of the stent graft constrained by the cap (premature stretching could create a gap large enough for the restrained members of the stent graft to spring loose. Additionally, a proximal lock (retainer) 22 is also coupled to a distal portion of the outer tube 18. The proximal lock 22 preferably includes at least one or a plurality of ribs (or splines) 23 that can together with the shroud portion 16 serve as an axial constraint for the end stent-graft 30. The proximal end (or the proximal springs 31, 32, and 33) of the stent-graft 30 cannot deploy until the proximal end of the ribs of the proximal lock clear the end of the shroud portion 16 of the tip.

[0036] A stent-graft can include a polyester or Dacron material (forming the graft material 34 (Fig 3B)) sewn to a Nitinol support structure 35 using polyester sutures. In one example, a Nitinol wire is used to form a skeletal structure 35 that provides support, strength and stability to the stent-graft. The stent-graft can also have a sup-

port member (crown stent or spring 36) on the proximal end of the stent-graft that is left mainly uncovered by the graft material. The uncovered portion will typically have a zig zag like pattern with a predetermined number of apices protruding up. The apices form the extreme end of what is known as the proximal spring (or crown spring 36) of the stent-graft.

[0037] As shown in FIGs. 1-3, the gap 19 between the backplate 17 and the proximal lock 22 is preferably designed to hold the protruding apices of the proximal spring. The apices straddle the ribs 23 of the proximal lock 22 and remain trapped between the back plate and the proximal lock until the relative movement between the outer tube 18 and the inner tube 20 exposes the gap 19 and releases the apices 31-33 of the proximal spring as shown in FIG. 4. In other words, the apices 31-33 cannot release from the ribs 23 on the proximal lock 22 while the apices remain within the shroud portion 15. When the inner tube 20 and tapered tip 12 assembly are advanced forward exposing the proximal lock 22, the apices of the proximal spring release from the respective ribs 23 of the proximal lock 22. The release results in the deployment of the proximal end of the stent-graft 30 as shown in FIG. 4. Note that while the apices of the proximal spring remain in gap 19 and within the cap or shroud portion of the tapered tip 12, the whole of the proximal spring remains axially (longitudinally) constrained as well as radially constrained. The support ring 13, usually made of metal, helps prevent the radial force of the proximal springs from distorting the shape of the tapered tip and particularly the shroud portion of the tapered tip.

[0038] Close up schematic plan views of another stent-graft deployment delivery system 50 are shown in FIGs. 5 and 6. FIG. 5 illustrates a plurality of proximal spring apices 65, 67 and 69 (68 is hidden in this view) of a stent-graft 63 constrained within a cap or shroud portion 55 of a tip 52. The cap or shroud portion 55 can be formed from the tube section 54 which can further include support ring 56.

[0039] FIG. 5A illustrates the backplate 57 in engagement with the inner tube assembly's proximal lock catch 64. The proximal lock catch 64 is a plate or bar which spans the end of the backplate 57 and has two engagement hooks to engage with engagement hook receiving slots or channels in the backplate 57. Two offset partial cross sectional views of these slots or channels can be seen on the right and left sides of the backplate 57 shown in FIG. 5A. The left side shows the left side protrusion from the lock catch 64 engaged in the slot and prevented from release by a slot lip, while the right side shows an angularly offset cross section (not diametrically opposite the left side) where the slot or channel is open and the slot lip is absent. The release of the catch 64 from engagement with the backplate. can be performed by a rotational motion by having an obliquely shaped slot similar to the channel as more precisely pictured in FIG. 7, below. Or by initiating a relative rotational

motion between the inner and outer tubes. While the proportions shown in the Figures are not consistent with the type of arrangement shown in FIG. 7, a person skilled in the art will recognize the schematic nature of the items presented in FIGs. 5, 5A, and 6, and understand that the proportions can be changed to include the functional engagement and disengagement action between the inner and outer tubes as presented and discussed for FIG. 7.

[0040] FIG. 6 illustrates another close up view of the stent-graft deployment delivery system 50 with the plurality of proximal spring apices 65, 67, 69 and 68 released from under the cap. As in system 10 described in FIGs 1-4, the stent-graft deployment delivery system 50 includes an outer tube 60 coupled to both a backplate 57 and a proximal lock 62 having a plurality of ribs 61, an inner tube 59 (within the outer tube 60) coupled to the tip 52, and a proximal lock catch 64 connected to the tip 52. When the inner tube 59 and tip 52 to which it is fixed are advanced forward exposing the proximal lock 62, the apices 65, 67, 69 and 68 of the proximal spring are release from the respective ribs (e.g., 61) of the proximal lock 62. The release results in the deployment of the proximal end of the stent-graft 63 as shown in FIG. 6.

[0041] While the apices 65, 67, 69 and 68 of the proximal spring are held in the gap between the backplate and proximal lock and within the cap or shroud portion of the tapered tip 52, the whole of the proximal spring remains axially constrained as well as radially constrained. The support ring 56, as previously explained helps prevent the radial force of the proximal springs from distorting the shape of the tip and particularly the shroud portion of the tip.

[0042] Now referring to FIG. 7, a perspective view of a proximal lock assembly 70 is shown including an inner tube 72 within an outer tube 74, a proximal lock 75, a backplate 78 and a proximal lock catch 80. The inner tube 72 is attached to the proximal lock catch 80 at a distal end of the inner tube 72. The proximal lock catch 80 can be connected to a tip of a stent-graft delivery system as previously shown schematically in FIGs. 5 and 6. The inner tube 72 further serves as a guidewire (not shown) lumen. The backplate 78 is attached at a distal end of the outer tube 74 with the proximal lock 75 being attached near the distal end of the outer tube 74 as shown. The backplate 78 serves as a proximal stop (preventing the stent graft from moving with the shroud and tip assembly when the shroud (cap) is moved forward to release the apices of the proximal spring) for a stent-graft (not shown) and preferably includes at least one channel 79. The proximal lock catch 80 can include at least one post 82 that rides in the channel 79 (disposed at an oblique angle with respect to the longitudinal axis of the stent graft and catheter, the channel (slot) being closed at the proximal end and open at the opposite end) of the backplate 78. With this arrangement, the proximal lock 75 cannot separate from the tip (and catch

80) (because of the closed proximal end of the channel) until the post or posts 82 are moved distally so that the end(s) of the posts (e.g., 82) are expelled from and clear the end of the channel or channels 79 so they no longer prevent proximal motion of the tip relative to the proximal lock 75. To release the catch 80, the proximal lock 75 and tip (or catch 80) must be forced together (or compressed) (the actuation mechanism actually has to be moved (turned) in the opposite direction to motion used for normal deployment), which is opposite the force that is provided during the normal deployment motion (a separation force). The clearing is accomplished by pulling (using the threaded deployment relative motion mechanism of the catheter described below) the inner tube 72 axially with respect to the outer tube so that the post 82 is forced out of the channel in the backplate and completely disengages (or escapes) the channel 79 in the backplate 78. Once a user compresses the tip (or catch 80) and proximal lock 75 releasing the catch 80 from the backplate 78, the proximal lock can be advanced out of the shroud portion of the tip. The distal mechanism for actuating the relative coaxial movement of the inner tube 72 and outer tube 74 (and the respective components of the assembly 70 respectively attached thereto) will become apparent with the description of FIGs. 8 and 9. Such an assembly prevents premature deployment and reduces the likelihood of an unintentional deployment of a stent-graft. This arrangement also prevents any elongation forces the deployment system could experience during tracking and/or deployment which could cause premature deployment.

[0043] The proximal lock 75 preferably includes a number of contoured ribs 76 about the periphery of the proximal lock 75. The number of ribs will ideally depend on the number of apices in a proximal spring of a stent-graft (not shown) although the present invention is not necessarily limited thereto. The contouring of the ribs 76 aid in the loading of the apices of the proximal spring onto the proximal lock (by providing an inclined surface such that a proximal end spring constrained in a fixture to a cylindrical shape can be mounted over the thin diameter end of the contour and then forced toward the wide end so that the contoured shape proximal lock is acting as an expansion mandrel, allowing the apices of the proximal spring to be forced past the wide end and be engaged by the end of the contoured splines, then the shroud can be introduced over the now proximal lock engaged apices of the proximal spring of the stent graft) and the wide end of the contoured splines further providing an axial constraint for the proximal end of the stent-graft until deployment when the proximal lock clears the shroud section of the tip as previously explained with respect to FIGS 1-6. The relative movement between the inner tube 72 and the outer tube 74 will cause the release of the proximal end (proximal springs) of the stent-graft. The contoured surface of the proximal lock also provides an advantage after the proximal end of the stent graft is released and the stent graft is fully

deployed, such that the taper of the outer surface makes it easier to retract the catheter tip back into the sheath, the contoured outer surface once the small diameter end begins access to the end of the sheath, acts as a guide to channel the sheath to coaxially surround the tip, so that contact and damage to vascular internal surfaces is minimized as the tip is retracted within the sheath.

[0044] Now referring to FIG. 8, a schematic diagram of a distal assembly or a spinning collar actuation assembly 100 is shown illustrating the controlled relative axial movement of an inner tube (e.g., 102) to an outer tube (e.g., 104). The assembly 100 preferably includes a luer 112 and spindle 110 attached to the inner tube (e.g., 102), a threaded shaft 108 and handle 114 coupled to the outer tube (e.g., 104), and a collar 106. The collar 106 can be attached to the inner tube (e.g., 102) and yet also spin in relation to the luer 112. In this configuration, the inner tube 102 can advance axially in relation to the outer tube 104 by screwing or spinning the collar 106 down or across the threaded shaft 108. The threaded shaft 108 can be similar to the threaded portion of a Touchy Borst connector commonly used in catheters. The assembly 100 provides a simple mechanism by twisting or spinning for release (or activation) of the apices of or the proximal spring of a stent graft during deployment.

[0045] A schematic diagram of a stent-graft deployment delivery system 900 including a tip 952 (coupled to an inner tube 961) having a cap or shroud portion formed from a tube section 954, an outer tube 960 coupled to both a backplate 957 and a proximal lock 962, as well as a distal assembly or a spinning collar actuation assembly is shown in FIG. 9. The distal assembly provides controlled relative axial movement of the inner tube 961 with respect to the outer tube 960 and preferably includes a luer 912 and spindle 910 attached to the inner tube 961, a threaded shaft 908 coupled to the outer tube 960, and a collar 906. The collar 906 can be attached to the inner tube 961 and yet also spin in relation to the luer 912. In this configuration, the inner tube 961 can advance axially in relation to the outer tube 960 by screwing or spinning the collar 906 down or across the threaded shaft 908. Note that a sheath and stent-graft are not shown in FIGs 8 and 9 and the sheath and its actuation mechanism and handle (not shown) are located around the inner and outer tubes as previously described between the stent graft proximal spring apices actuation handle (mechanism) and the tip of the catheter where the stent graft is deployed.

[0046] When treating Abdominal Aortic Aneurysms (AAA), for example, there are several anatomical challenges when advancing a stent-graft deployment system or device and appropriately placing the stent-graft itself. A major challenge is encountered in the region of the aortic bifurcation (this typically includes the femoral, external iliac, and common iliac arteries). Existing stent-graft delivery systems that deploy from a distal end of

the stent-graft fail to provide sufficient options for re-alignment once the stent-graft is even partially deployed. Existing stent-graft delivery systems that deploy from a proximal end of the stent-graft fail to provide adequate control in the eventual release of the proximal end of the stent-graft. Stent-grafts that require alignment of ports with branch arteries can use the re-deployment capabilities and the controlled release mechanisms of the present invention to a great advantage. Since the system of the present invention constrains the proximal end of the stent-graft radially while allowing the middle and/or distal portions of the stent-graft to deploy first, the stent-graft can be repositioned both axially and radially by preventing the stent-graft from fixating itself to a vessel, even when partially deployed.

[0047] Stent-grafts that require alignment with branch arteries can have the middle or port areas of the stent-graft release first. The stent-graft can be realigned so that all ports are properly aligned before releasing the proximal end of the stent-graft. The proximal end of the stent-graft is also axially constrained which enables the delivery system to maintain the position of the stent-graft during the full deployment sequence even if the stent-graft has little or no axial support. Since the present invention fixes the proximal end of the stent-graft during deployment while the sheath is withdrawn, the frictional forces between the stent-graft and sheath cause the stent-graft to be held under a tensile load. While under a tensile load, the density of the stent-graft and the compressive forces within the sheath are reduced. Additionally, using the design of the present invention, deployment forces can be further reduced by removing supports (such as connecting bars) in the stent-graft since such supports would no longer be needed for deployment.

[0048] Additionally, the description above is intended by way of example only and is not intended to limit the spirit and scope of the invention and it equivalent as understood by persons skilled in the art.

Claims

1. A controlled stent-graft deployment delivery system (10; 50; 900), comprising:
 - a stent-graft (30; 63);
 - a retractable primary sheath (40) containing said stent-graft in a first constrained diameter configuration;
 - an outer tube (18; 60) within the retractable primary sheath and within the stent-graft;
 - an inner tube (20; 59) within the outer tube, wherein the inner tube and the outer tube both axially can move relative to the retractable primary sheath and to each other;
 - a cap (15; 55) coupled to a distal end of the inner tube and configured to retain at least a por-

tion of a proximal portion of the stent-graft in a radially compressed configuration, wherein a controlled relative axial movement between the outer tube and the inner tube releases the proximal end of the stent-graft from the cap and from the radially compressed configuration.

2. The controlled stent-graft deployment delivery system of **claim 1**, wherein the cap is a shroud portion of a flexible tapered tip (12) fixed to the distal end of the inner tube.
3. The controlled stent-graft deployment delivery system of any of **claims 1 to 2**, wherein a threaded collar coupled to the inner tube and a mating threaded shaft coupled to the outer tube enables the relative axial movement between the inner tube and the outer tube for controlled deployment of the stent-graft.
4. The controlled stent-graft deployment delivery system of any of **claims 1 to 3** further comprising a proximal lock (22; 62; 75) attached to the outer tube, wherein the stent-graft has a plurality of proximal spring apices at the proximal end of the stent-graft that remain latched onto the proximal lock in the radially compressed configuration while the plurality of spring apices remain within the cap.
5. The controlled stent-graft deployment delivery system of **claim 4**, wherein the proximal lock further comprises a plurality of ribs (23; 61; 75) for retaining a plurality of apices of the proximal spring of the stent-graft.
6. The controlled stent-graft deployment delivery system of **claim 5**, wherein the plurality of ribs are each tapered to aid in the process of re-introducing the proximal lock into the retractable primary sheath after deployment of the stent-graft.
7. A controlled stent-graft deployment delivery system, comprising:
 - a retractable primary sheath (40);
 - an outer tube (18; 60) within the retractable primary sheath;
 - an inner tube (20; 59) within the outer tube, wherein the inner tube can move axially relative to the outer tube;
 - a cap (15; 55) axially fixed to a distal end of the inner tube; and
 - a retention mechanism attached to the outer tube for retaining a proximal end of a stent-graft in a constrained diameter configuration while the end of the stent-graft is still located within the cap while still enabling axial and radial movement of the stent-graft.

8. The controlled stent-graft deployment delivery system of **claim 7**, wherein the retention mechanism enables a partial deployment of a remaining distal portion of the stent-graft while maintaining the proximal end of the stent-graft in the constrained diameter configuration 5
9. The system of any of **claims 7 to 8**, wherein retention mechanism comprises a proximal lock (22;62) fixed to the outer tube. 10
10. The system of any of **claims 7 to 9**, wherein the cap is formed from a shroud portion of a tapered tip coupled to the distal end of the inner tube. 15
11. The system of **claim 9**, wherein the proximal lock includes a plurality of ribs (23; 61) for retaining a plurality of apices of the proximal spring of the stent-graft. 20
12. The system of any of **claims 7 to 11**, wherein the system further comprises means for controlled co-axial movement of the inner tube relative to the outer tube. 25
13. The system of **claim 12**, wherein the means for controlled coaxial movement comprises a spinning collar attached to the inner tube that causes a proximal lock to move in and out of the shroud portion of the tip by advancing along a threaded member attached to the outer tube. 30
14. The system of any of **claims 7 to 13**, wherein the retention mechanism further comprises a back plate (17; 57; 78) having a channel (79) and a proximal lock (64; 80) catch which couples the proximal lock with the cap until the proximal lock catch is released from the channel of the back plate. 35
15. The system of any of **claims 7 to 14**, wherein the system further comprises a second retention mechanism for retaining a distal end on the stent-graft undeployed while a remaining portion of the stent-graft is deployed. 40
16. A method for controlled deployment of a stent-graft, comprising the steps of: 45
- constraining a proximal end of a stent-graft radially under a cap while partially deploying a remaining portion of the stent-graft; 50
- adjusting at least one of the axial and radial positions of the stent-graft after the partial deployment the remaining portion; and
- releasing the proximal area of the stent-graft by controlled coaxial movement between the cap and a tube retaining the stent-graft within the cap. 55
17. The method of **claim 16**, wherein the constraining step further comprises the step of constraining proximal springs of the stent-graft between a shroud area of a proximal tip and a proximal lock coupled to an inner tube.
18. The method of any of **claims 16 to 17**, wherein the constraining step further comprises the step of constraining a plurality of apices of a proximal spring of the stent-graft between a shroud area of a proximal tip and a proximal lock having ribs.
19. A controlled stent-graft (30; 63) deployment delivery system (10; 50; 900), comprising:
- a self expanding stent-graft compressed on a delivery system, the stent graft having a proximal spring having apices extending proximally therefrom;
- a proximal lock (22; 62; 75) fixed to an outer tube of said delivery system, said proximal lock having protrusions over which said apices extend at the proximal end of the stent graft
- a shroud (15; 55) fixed to a distal end of an inner tube of said delivery system and surrounding at least a portion of a proximal portion of apices of a spring of the stent-graft in a radially compressed configuration and in close proximity to the radial ends of the protrusions so that the stent graft spring apices are prevented from releasing, wherein a controlled relative axial movement between the outer tube and the inner tube releases the proximal end of the stent-graft from the shroud.
20. The controlled stent-graft deployment delivery system, as in **Claim 19**, further comprising:
- a proximal lock catch (64; 80) coupling the inner and outer tube at a proximal end of said stent graft, the coupling is initially engaged and prevents the shroud from moving axially to clear the proximal end of the stent graft;
- wherein said controlled axial movement in a first direction causes the catch to uncouple the inner and outer tubes, while said controlled axial movement in a second direction opposite said first direction, after said first and second tubes have been uncoupled, causes the shroud to move to clear the proximal end of the stent graft.
21. The controlled stent-graft deployment delivery system, as in **Claim 20**, wherein said controlled axial movement is caused through a threaded engagement between the inner tube and the outer tube at a handle end of said delivery system.

22. A controlled stent-graft deployment delivery method comprising:

inserting a self expanding stent graft inside a
stent graft delivery system into a vessel pas- 5
sage;
performing a partial deployment of the stent
graft;
releasing a proximal lock catch of a stent graft
proximal end retaining system by causing a in- 10
ner tube connected to a first component of said
catch to move in a first axial direction with re-
spect to a first component coupling component
connected to an outer tube;
releasing the proximal end of the stent graft by 15
moving the inner tube in a second axial direc-
tion with respect to the outer tube.

23. The controlled stent-graft deployment delivery
method of **Claim 22**,

wherein causing the inner tube to move rela- 20
tive to the outer tube is accomplished by rotating
relative to one another interengaged threaded ele-
ments at a handle end of said system, where a first
of said interengaged threaded elements is coupled 25
to said inner tube and a second of said interen-
gaged threaded elements is coupled to said outer
tube.

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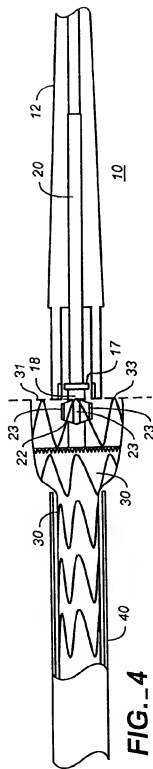
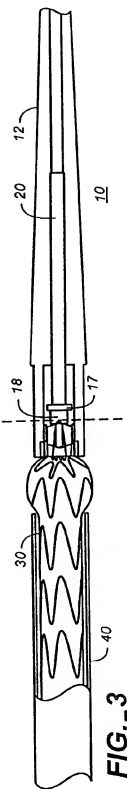
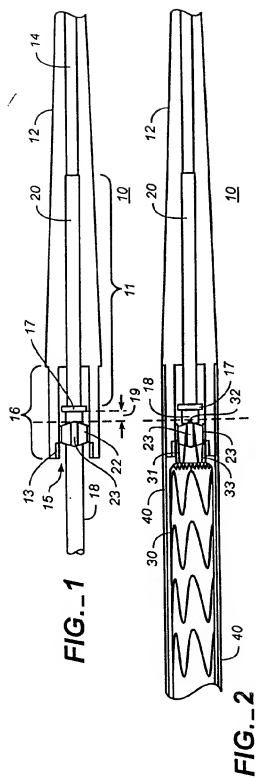
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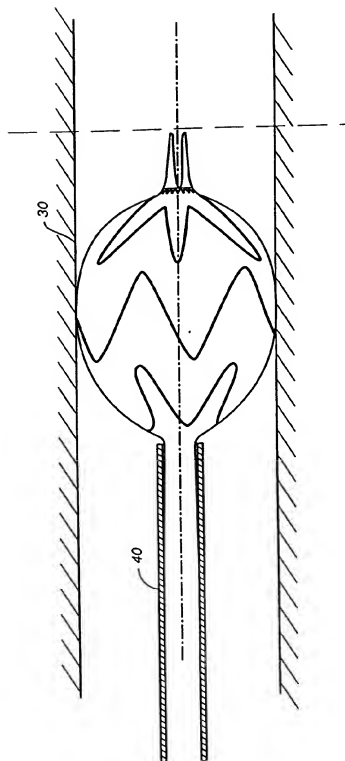


FIG. 3A

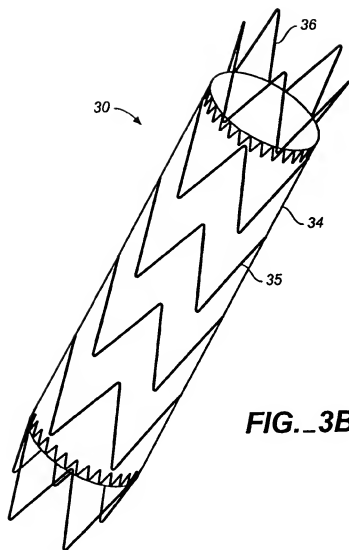
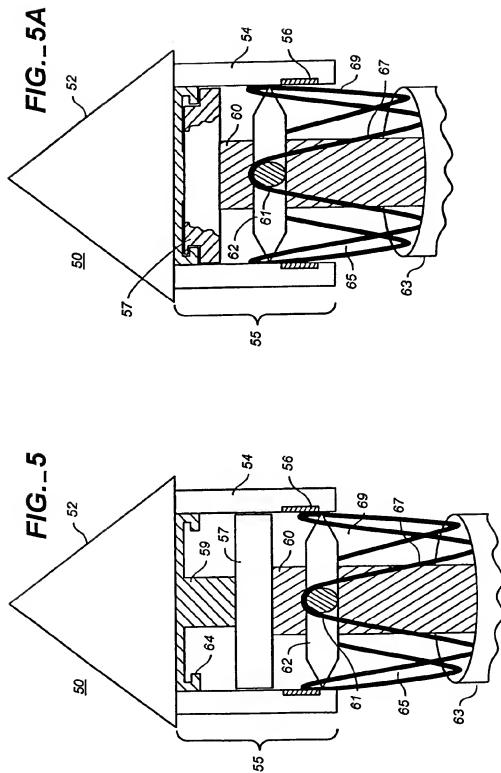
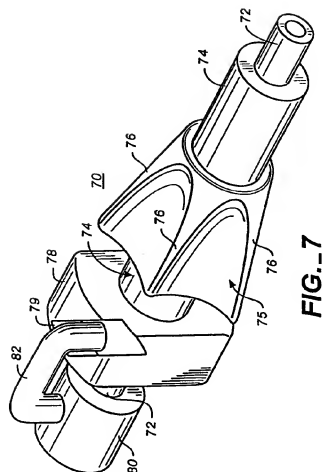
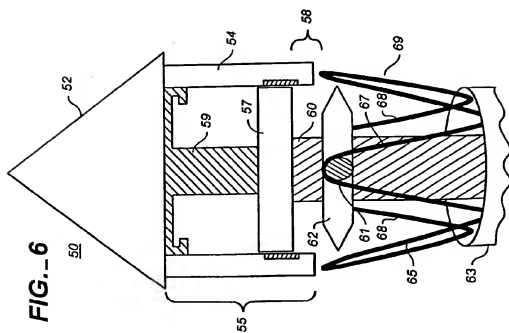
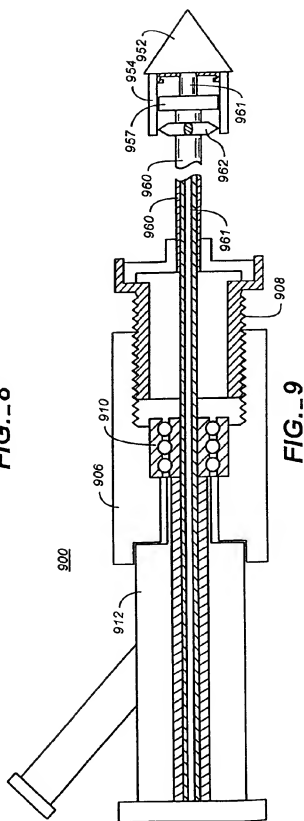
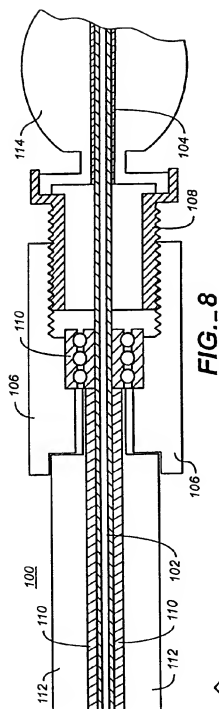


FIG. 3B









European Patent
Office

PARTIAL EUROPEAN SEARCH REPORT

Application Number

which under Rule 45 of the European Patent Convention EP 03 01 2920
shall be considered, for the purposes of subsequent
proceedings, as the European search report

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
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A	WO 01 17458 A (ANGIOMED AG) 15 March 2001 (2001-03-15) * the whole document *	1,7,19	
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			A61F
INCOMPLETE SEARCH			
<p>The Search Division considers that the present application, or one or more of its claims, does/cdo not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for these claims.</p> <p>Claims searched completely : 1-15,19-21</p> <p>Claims searched incompletely : Claims not searched : 16-18,22,23</p> <p>Reason for the limitation of the search: Article 52 (4) EPC - Method for treatment of the human or animal body by surgery</p>			
Place of search		Date of completion of the search	Examiner
THE HAGUE		25 September 2003	Smith, C
CATEGORY OF CITED DOCUMENTS			
<p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons</p> <p>& : member of the same patent family, corresponding document</p>			

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**ANNEX TO THE EUROPEAN SEARCH REPORT
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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

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(54) **Stent-graft delivery system**

(57) A method of delivering a stent-graft (108) includes mounting the stent-graft on a pushrod (106; 106A); radially constraining the stent-graft within a sheath (112); securing a crown portion (118) of the stent-graft to the pushrod with a retainer structure (122) of a stent-graft retention system; retracting the sheath to

expose the crown portion (118) of the stent-graft; and further retracting the sheath to cause the retainer structure to release the crown portion from the pushrod thus deploying the stent-graft. The retainer structure releases the stent-graft automatically as a result of the retraction of the sheath.

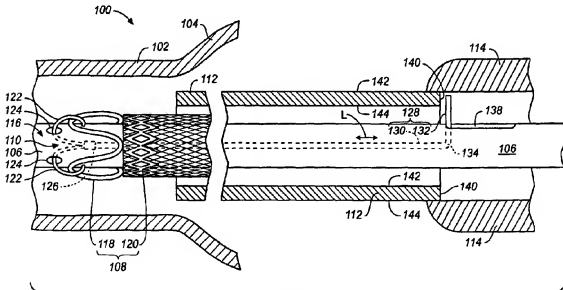


FIG. 2

Description

[0001] The present invention relates to an intra-vascular device and method. More particularly, the present invention relates to a device for deployment of a stent-graft for treatment of intra-vascular aneurysms. Specifically, it relates to a stent-graft delivery system, a stent-graft retainment system, and a method of handling a stent-graft.

[0002] In stent-graft deployment systems, a self-expanding stent-graft is restrained within a sheath. After placement of the stent-graft at the desired location via fluoroscopic guidance, the physician retracts the sheath to deploy the stent-graft, i.e., to expose the stent-graft and allow it to self-expand.

[0003] However, prior to deployment, the compressed stent-graft tends to press outwards on the inner surface of the sheath because of its high radial force, self-expanding design. As a result, significant deployment force is required to retract the sheath to deploy the stent-graft.

[0004] This significant deployment force puts significant stress on the stent-graft, which can result in damage or destruction of the stent-graft during deployment. Further, this significant deployment force places significant stress on the delivery system, which can lead to component failure of the delivery system.

[0005] The present invention intends to overcome at least some of the above problems. The object is solved by the stent-graft delivery system according to independent claims 1 and 27, by the stent-graft retainment system according to independent claim 19, and by the method according to independent claim 22.

[0006] Further advantages, features, aspects and details of the invention are evident from the dependent claims, the description and the drawings.

[0007] In one embodiment according to the present invention, a method of delivering a stent-graft includes mounting the stent-graft on a pushrod; radially constraining the stent-graft within a sheath; securing a crown portion of the stent-graft to the pushrod with a retainer structure of a stent-graft retainment system; retracting the sheath to expose the crown portion of the stent-graft; and further retracting the sheath to cause the retainer structure to release the crown portion from the pushrod thus deploying the stent-graft.

[0008] The retainer structure releases the stent-graft automatically as a result of the retraction of the sheath. Thus, in accordance with this embodiment of the present invention, exposure of the crown portion of the stent-graft by retraction of the sheath is followed by release of the crown portion of the stent-graft by the retainer structure without requiring any additional manipulations by the physician compared to a conventional stent-graft delivery system.

[0009] Since the retainer structure holds the crown portion against the pushrod during initial retraction of the sheath, the normal force exerted by the crown portion

of the stent-graft against the sheath is minimized. Since this normal force is minimized, graft-to-sheath friction is minimized thus minimizing the stent-graft deployment (sheath retraction) force.

[0010] By minimizing the deployment force, the stress on the stent-graft is minimized thus minimizing the possibility of damaging the stent-graft during deployment. Further, by minimizing the deployment force, the stress on the stent-graft delivery system is minimized thus also minimizing the possibility of damaging the stent-graft delivery system during deployment of the stent-graft.

[0011] In another embodiment according to the present invention, a stent-graft delivery system includes: a pushrod having a lumen and a trigger aperture; a stent-graft retainment system having a retainer structure, and a retainer release trigger coupled to the retainer structure, the retainer release trigger including a trigger portion extending radially from the lumen through the trigger aperture; and a sheath having a trigger trip surface.

[0012] In yet another embodiment according to the present invention, a stent-graft retainment system includes: a retainer structure; and a retainer release trigger coupled to the retainer structure, the retainer release trigger having a pull rod portion coupled to a trigger portion.

[0013] Yet, another embodiment provides a method of delivering a stent-graft includes mounting the stent-graft on a pushrod; radially constraining the stent-graft within a sheath; securing a crown portion of the stent-graft to the pushrod with a retainer structure of a stent-graft retainment system; retracting the sheath to expose the crown portion of the stent-graft; and further retracting the sheath to cause the retainer structure to release the crown portion from the pushrod thus deploying the stent-graft. The retainer structure releases the stent-graft automatically as a result of the retraction of the sheath.

[0014] The invention is also directed to apparatuses for carrying out the disclosed methods and including apparatus parts for performing each described method steps. These method steps may be performed by the way of hardware components or in any other manner. Furthermore, the invention is also directed to methods by which the described apparatus operates or is fabricated. It includes method steps for carrying out every function of the apparatus or manufacturing every part of the apparatus.

[0015] The present invention is best understood by reference to the following detailed description when read in conjunction with the accompanying drawings. Therein,

FIG. 1 is a modified partial cross-section view of a stent-graft delivery system within a parent vessel of a patient adjacent to a fistula aneurysm;
FIG. 2 is a modified partial cross-section view of the stent-graft delivery system of FIG. 1 during deploy-

ment of the stent-graft;

FIG. 3 is a modified partial cross-section view of the stent-graft delivery system of FIG. 2 at a further stage during deployment of the stent-graft;

FIG. 4 is a modified partial cross-section view of a region of a stent-graft delivery system;

FIG. 5 is a partial side view of a stent-graft delivery system having a crown portion of a stent-graft engaged with a stent-graft retainment system;

FIG. 6 is a side partial cross-section view of a region VI of the delivery system of FIG. 5;

FIG. 7 is a side partial cross-section view of the region VI of the delivery system of FIG. 6 during deployment of the stent-graft; and

FIGS. 8 and 9 are side partial cross-section views of a region of a stent-graft delivery system during deployment of a stent-graft.

[0016] Common reference numerals are used throughout the drawings and detailed description to indicate like elements.

[0017] In one embodiment according to the present invention, a method of delivering a stent-graft 108 includes mounting stent-graft 108 on a pushrod 106 (FIG. 1); radially constraining stent-graft 108 within a sheath 112; securing a crown portion 118 of stent-graft 108 to pushrod 106 with a retainer structure 122 of a stent-graft retainment system 110; retracting sheath 112 to expose crown portion 118 of stent-graft 108 (FIG. 2); and further retracting sheath 112 to cause retainer structure 122 to release crown portion 118 from pushrod 106 thus deploying stent-graft 108 (FIG. 3).

[0018] Retainer structure 122 releases stent-graft 108 automatically as a result of the retraction of sheath 112. Thus, exposure of crown portion 118 by sheath 112 (FIG. 2) followed by release of crown portion 118 by retainer structure 122 (FIG. 3) does not require any additional manipulations by the physician compared to a conventional stent-graft delivery system.

[0019] More particularly, FIG. 1 is a modified partial cross-section view of a stent-graft delivery system 100 within a parent vessel 102 of a patient adjacent to a fistula aneurysm 104. Illustratively, fistula aneurysm 104 is an intra-cranial or aortic aneurysm although other aneurysms are treated in other embodiments.

[0020] Delivery system 100 includes a pushrod 106, a stent-graft 108, a stent-graft retainment system 110, a sheath 112, and a delivery handle 114.

[0021] In accordance with this embodiment, pushrod 106, sometimes called an inner catheter, is a hollow tubular member and includes a lumen 116, e.g., a guide wire lumen. In one embodiment (not shown), pushrod 106 includes an expandable catheter balloon for expanding and anchoring stent-graft 108 within parent vessel 102 as those of skill in the art will understand in light of this disclosure. However, for purposes of simplicity, stent-graft 108 is discussed below as being a self-expanding stent-graft.

[0022] Stent-graft 108 is placed over and mounted on pushrod 106. In one embodiment, pushrod 106 and/or stent-graft 108 include radiopaque markers, which allow the location of stent-graft 108 to be precisely tracked facilitating positioning of stent-graft 108 within parent vessel 102.

[0023] Stent-graft 108 is radially constrained by sheath 112. More particularly, prior to deployment, stent-graft 108 is located within sheath 112. Sheath 112 is coupled, e.g., with adhesive, to delivery handle 114.

[0024] Stent-graft 108 includes a crown portion 118, sometimes called a bare stent portion, at a proximal (upstream) end (with respect to an aortic deployment) of stent-graft 108. Stent-graft 108 further includes a stent-graft portion 120 coupled to crown portion 118.

[0025] Crown portion 118 of stent-graft 108 is secured to pushrod 106 by stent-graft retainment system 110. More particularly, crown portion 118 of stent-graft 108 is secured to pushrod 106 by a retainer structure 122, sometimes called a retainment means or means for retaining, of stent-graft retainment system 110.

[0026] Retainer structure 122 is a plurality of curved wires, sometimes called hooks, extending from lumen 116 through corresponding retainer apertures 124 of pushrod 106. Generally, retainer structure 122 includes at least one curved wire. Retainer structure 122 is formed of a rigid material, e.g., steel or spring steel, having a sufficient rigidity and strength to hold crown portion 118 of stent-graft 108 in place.

[0027] The plurality, e.g., two or more, of curved wires of retainer structure 122 are connected together by a trigger wire coupler 126 of stent-graft retainment system 110 at a proximal (downstream) end of retainer structure 122. The plurality of curved wires of retainer structure 122 extend distally (upstream) and outwards from trigger wire coupler 126. The plurality of curved wires of retainer structure 122 pass out from lumen 116 through corresponding retainer apertures 124 of pushrod 106 and curve to extend over crown portion 118 and back in the proximal (downstream) direction. However, in another embodiment (not shown), the plurality of wires of retainer structure 122 pass out from lumen 116 proximally (downstream) of crown portion 118 and extend over crown portion 118 in the distal (upstream) direction.

[0028] Stent-graft retainment system 110 further includes a retainer release trigger 128 coupled to retainer structure 122 by trigger wire coupler 126. Retainer release trigger 128, sometimes called a graft release trigger, is formed of a rigid material, e.g., a steel wire, having a sufficient rigidity and strength to cause retraction of retainer structure 122.

[0029] Although retainer structure 122 is illustrated and discussed above as being coupled to retainer release trigger 128 by trigger wire coupler 126, in another embodiment, retainer structure 122 and retainer release trigger 128 are integral, i.e., are a single piece not a plurality of separate pieces coupled together.

[0030] In the embodiment illustrated in FIG. 1, retainer

release trigger 128 comprises a pull rod portion 130 and a trigger portion 132 coupled together at a bend portion 134. In this embodiment, pull rod portion 130, trigger portion 132 and bend portion 134 are integral, but can be separate pieces connected together in another embodiment.

[0031] A distal (upstream) end of pull rod portion 130 is coupled to trigger wire coupler 126. Pull rod portion 130 extends longitudinally in the proximal direction from trigger wire coupler 126 through lumen 116 of pushrod 106. Pull rod portion 130 is coupled to trigger portion 132 at a proximal (downstream) end of pull rod portion 130.

[0032] Generally, pull rod portion 130 extends along the length of longitudinal axis L of pushrod 106 and thus pull rod portion 130 is sometimes said to extend longitudinally or in the longitudinal direction. Trigger portion 132 extends in a direction perpendicular to longitudinal axis L of pushrod 106 and thus trigger portion 132 is sometimes said to extend radially or in the radial direction. Bend portion 134 bends from the longitudinal direction to the radial direction.

[0033] Pushrod 106 further comprises a trigger aperture 138. In this embodiment, trigger aperture 138 is a longitudinal slot in pushrod 106. Trigger portion 132 extends radially from lumen 116 of pushrod 106 and through trigger aperture 138. Trigger portion 132 extends radially outwards from pushrod 106 a radial distance TP, sometimes called a first radial distance. The radial distance S, sometimes called a second radial distance, between sheath 112 and pushrod 106 is less than the distance TP of trigger portion 132. Thus, sheath 112 contacts trigger portion 132 during retraction. Pull rod portion 130 is positioned within pushrod 106, for example, by splitting and rejoining the radial sections of pushrod 106. A separate lumen within pushrod 106 guides the motion of pull rod portion 130 in one embodiment.

[0034] However, to prevent trigger portion 132 from contacting delivery handle 114, the radial distance DH, sometimes called a third radial distance, between delivery handle 114 and pushrod 106 is greater than the distance TP of trigger portion 132. This allows delivery handle 114 to be moved without contacting trigger portion 132 as discussed in greater detail below.

[0035] More particularly, sheath 112 comprises an annular trigger trip surface 140, which is perpendicular to longitudinal axis L of pushrod 106. Trigger trip surface 140 is located at the proximal (downstream) end of sheath 112 and extends between an inner surface 142 and an outer surface 144 of sheath 112. Prior to retraction of sheath 112, a longitudinal trigger trip distance TTD exists between trigger trip surface 140 and trigger portion 132. Although trigger trip surface 140 is discussed and illustrated herein as being a surface of sheath 112, in an alternative embodiment (not shown), trigger trip surface 140 is a surface of a different element of delivery system 100, e.g., of delivery handle 114.

[0036] FIG. 2 is a modified partial cross-section view

of stent-graft delivery system 100 during deployment of stent-graft 108. Referring now to FIGS. 1 and 2 together, to deploy stent-graft 108, delivery handle 114 is retracted. Since sheath 112 is coupled to delivery handle 114, retraction of delivery handle 114 causes retraction of sheath 112.

[0037] Since retainer structure 122 holds crown portion 118 against pushrod 106, the large normal force which would otherwise be exerted by crown portion 118 of stent-graft 108 against inner surface 142 of sheath 112 is minimized. Since the normal force is minimized, graft-to-sheath friction is minimized thus minimizing the deployment force, i.e., the force exerted upon delivery handle 114 during retraction. In addition, a reduction in the normal force minimizes any embedding (mechanical engagement) of stent-graft 108 into sheath 112, which further minimizes the deployment force.

[0038] By minimizing the deployment force, the stress on stent-graft 108 is minimized thus minimizing the possibility of damaging stent-graft 108 during deployment. Further, by minimizing the deployment force, the stress on delivery system 100 is minimized thus also minimizing the possibility of damaging delivery system 100 during deployment of stent-graft 108. For example, stretching of sheath 112 and the associated possibility of necking of sheath 112 (diameter reduction) and/or failures at bonds between components, e.g., between sheath 112 and delivery handle 114, are minimized by minimizing the deployment force.

[0039] Further, stent-graft 108 is placed in tension rather than compression during deployment. More particularly, stent graft 108 is pulled proximally (downstream) from crown portion 118 and retainer structure 122 by sheath 112 during deployment. This minimizes the possibility of bunching of stent-graft 108.

[0040] After delivery handle 114 and the sheath 112 are retracted, i.e., moved, trigger trip distance TTD, sheath 112 contacts trigger portion 132 as shown in FIG. 2. More particularly, trigger trip surface 140 contacts trigger portion 132 and thus further retraction of delivery handle 114 and sheath 112 causes an equal retraction of trigger portion 132.

[0041] FIG. 3 is a modified partial cross-section view of stent-graft delivery system 100 of FIG. 2 at a further stage during deployment of stent-graft 108. Referring now to FIGS. 2 and 3 together, further retraction of delivery handle 114 and sheath 112 causes retraction of trigger portion 132 and release of crown portion 118 of stent-graft 108.

[0042] More particularly, retraction of trigger portion 132 causes proximal (downstream) towards delivery handle 114) longitudinal motion of pull rod portion 130. This, in turn, causes proximal longitudinal motion of trigger wire coupler 126 and retraction of the plurality of curved wires of retainer structure 122, i.e., causes retraction of retainer structure 122, into pushrod 106.

[0043] As retainer structure 122 is retracted to expose crown portion 118, crown portion 118 is released from

pushrod 106 by retainer structure 122. Since sheath 112 has also been retracted to expose crown portion 118, crown portion 118 self-expands into contact with parent vessel 102. Further retraction of delivery handle 114 and sheath 112 completes deployment of stent-graft 108.

[0044] As discussed above, retainer structure 122 releases stent-graft 108 automatically during retraction of delivery handle 114. Thus, use of stent-graft delivery system 100 including stent-graft retainment system 110 does not require any additional operations (manipulation) by the physician compared to a conventional stent-graft delivery system.

[0045] Further, referring again to FIG. 1, trigger trip distance TTD controls how much of stent-graft 108 is exposed by sheath 112 prior to release by retainer structure 122. Accordingly, by appropriately defining trigger trip distance TTD, stent-graft 108 is released after a desired amount of stent-graft 108 is exposed by sheath 112.

[0046] For example, stent-graft 108 is released after sheath 112 has uncovered and exposed the first few stent rings, e.g., crown portion 118 and the most proximal 2 to 4 stent rings, of stent-graft 108. Crown portion 118 and the first few stent rings of stent-graft 108 cause the highest normal friction and associated deployment force. Thus, by restraining crown portion 118 against pushrod 106 by retainer structure 122 during retraction of sheath 112 over the first few stent rings, a significant benefit is obtained. Further, this allows the physician to uncover the first stent rings and assess the position of stent-graft 108 in parent vessel 102 before releasing crown portion 118 and sealing the stent-graft 108 in parent vessel 102.

[0047] FIG. 4 is a modified partial cross-section view of a region of a stent-graft delivery system 100A of another embodiment according to the present invention. Retainer release trigger 128A of stent-graft retainment system 110A of stent-graft delivery system 100A includes a locking feature 402, sometimes called a locking means, for securing trigger portion 132 to sheath 112.

[0048] More particularly, locking feature 402 and trigger portion 132 are coupled together at a bend portion 404. In this configuration, trigger portion 132, locking feature 402, and bend portion 404 are integral, but can be separate pieces connected together in another embodiment.

[0049] A proximal (downstream) end of locking feature 402 is coupled to trigger portion 132 by bend portion 404. Locking feature 402 extends in the distal (upstream) direction from trigger portion 132.

[0050] When trigger portion 132 is engaged with trigger trip surface 140 of sheath 112 as illustrated in FIG. 4, locking feature 402 is adjacent to outer surface 144 of sheath 112. This locks retainer release trigger 128A around the proximal end of sheath 112 thus ensuring that retainer release trigger 128A does not slip from sheath 112. Delivery handle 114 is configured to accommodate the positioning of locking feature 402, e.g., by

providing a space 406 between delivery handle 114 and outer surface 144 of sheath 112.

[0051] FIG. 5 is a partial side view of a stent-graft delivery system 100B having crown portion 118 of stent-graft 108 engaged with a stent-graft retainment system 110B of another embodiment according to the present invention. Delivery system 100B is similar to delivery system 100 of FIGS. 1, 2, and 3 and so various elements, e.g., sheath 112, are not illustrated in FIG. 5. FIG. 6 is a side partial cross-section view of a region VI of delivery system 100B of FIG. 5.

[0052] Referring now to FIGS. 5 and 6 together, pushrod 106A comprises at least one trench 500 extending partially or completely around the circumference of pushrod 106A. Further, a retainer structure 122A comprises straight wires 502 (only a wire 502 and a wire 502A of the plurality of wires 502 are illustrated in FIG. 5) extending across trench 500 of pushrod 106A. Generally, retainer structure 122A includes at least one wire 502.

[0053] More particularly, trench 500 is defined by a proximal (partial or full) annular surface 504, e.g., at least one proximal annular surface, a distal (partial or full) annular surface 506, e.g., at least one distal annular surface, and a longitudinal (partial or full) ring surface 508, e.g., at least one longitudinal ring surface. In this embodiment, proximal annular surface 504 and distal annular surface 506 are perpendicular to longitudinal axis L of pushrod 106A. Further, longitudinal ring surface 508 is parallel to longitudinal axis L of pushrod 106A.

[0054] Proximal annular surface 504 and distal annular surface 506 includes proximal retainer apertures 510 (only a proximal retainer aperture 510 and a proximal retainer aperture 510A of the plurality of proximal retainer apertures 510 are illustrated in FIG. 5) and corresponding distal retainer apertures 512 (only a distal retainer aperture 512 and a distal retainer aperture 512A of the plurality of distal retainer apertures 512 are illustrated in FIG. 5), respectively. Wires 502 extend distally from pushrod 106A through proximal retainer apertures 510, longitudinally across trench 500, and back into pushrod 106A through distal retainer apertures 512.

[0055] To illustrate, a first wire 502A of the plurality of wires 502 extends distally from pushrod 106A through a first proximal retainer aperture 510A of the plurality of proximal retainer apertures 510, longitudinally across trench 500, and back into pushrod 106A through a first distal retainer aperture 512A of the plurality of distal retainer apertures 512 as shown in FIGS. 5 and 6.

[0056] FIG. 7 is a side partial cross-section view of region VI of delivery system 100B of FIG. 6 during deployment of stent-graft 108.

[0057] Referring now to FIGS. 5, 6, and 7 together, proximal annular surface 504, distal annular surface 506, longitudinal ring surface 508 and wires 502 define pockets 514 (only a pocket 514 and a pocket 514A of the plurality of pockets 514 are illustrated in FIGS. 5, 6,

7). Prior to deployment of stent-graft 108, crown portion 118 is retained within pockets 514.

[0058] To illustrate, proximal annular surface 504, distal annular surface 506, longitudinal ring surface 508 and wire 502A define a first pocket 514A of the plurality of pockets 514. A loop 516 of crown portion 118 passes through pocket 514A and presses radially outwards on wire 502A.

[0059] To deploy stent-graft 108, trigger wire coupler 126 is retracted as discussed above in reference to FIGS. 2 and 3. This causes retraction of wires 502 of retainer structure 122A. More particularly, wires 502 are retracted out of distal retainer apertures 512 and into proximal retainer apertures 510. Stated another way, wires 502 are retracted thus opening pockets 514. This releases crown portion 118 of stent-graft 108 resulting in deployment of stent-graft 108 as shown in FIG. 7.

[0060] In another embodiment, direct contact between crown portion 118 and retractable wires 502 is avoided. FIGS. 8 and 9 are side partial cross-section views of a region of a stent-graft delivery system 100C during deployment of stent-graft 108 according to another embodiment of the present invention.

[0061] Referring now to FIGS. 8 and 9 together, swings 800 are pivotally attached to distal annular surface 506 and extend across localized portions of trench 500. The number of swings 800 corresponds to the number of wires 502 around pushrod 106A. As shown in FIG. 8, crown portion 118 presses upon swings 800 which, in turn, press upon wires 502.

[0062] To deploy stent-graft 108, wires 502 are retracted as discussed above. More particularly, wires 502 are retracted out of distal retainer apertures 512 and into proximal retainer apertures 510. Stated another way, wires 502 are retracted thus opening pockets 514. This releases swings 800, which pivot from distal annular surface 506. This, in turn, releases crown portion 118 of stent-graft 108 resulting in deployment of stent-graft 108 as shown in FIG. 9.

[0063] In one embodiment, the coefficient of friction between swings 800 and wires 502 is less than the coefficient of friction between crown portion 118 and wires 502. Accordingly, use of swings 800 minimizes deployment force.

[0064] This disclosure provides exemplary embodiments of the present invention. The scope of the present invention is not limited by these exemplary embodiments. Numerous variations, whether explicitly provided for by the specification or implied by the specification or not, such as variations in structure, dimension, type of material and manufacturing process may be implemented by one of skill in the art in view of this disclosure.

Claims

1. A stent-graft delivery system comprising:

a pushrod (106; 106A) comprising:

a lumen; and
a trigger aperture (124);

a stent-graft retention system (110; 110B) comprising:

a retainer structure (122, 122A); and
a retainer release trigger (128; 128A) coupled to said retainer structure,

said retainer release trigger comprising a trigger portion (132) extending radially from said lumen through said trigger aperture; and
a sheath (112) comprising a trigger trip surface.

2. The stent-graft delivery system of Claim 1 wherein a longitudinal trigger trip distance exists between said trigger trip surface and said trigger portion prior to retraction of said sheath.

3. The stent-graft delivery system of any of the preceding claims wherein said trigger portion extends radially outwards from said pushrod a first radial distance, and wherein a second radial distance exists between said pushrod and said sheath, said first radial distance being greater than said second radial distance.

4. The stent-graft delivery system of Claim 3 wherein said trigger trip surface contacts said trigger portion during retraction of said sheath.

5. The stent-graft delivery system of any of the preceding claims wherein said retainer release trigger further comprises a pull rod portion (130) coupled to said trigger portion, said pull rod portion extending longitudinally through said lumen.

6. The stent-graft delivery system of Claim 5 wherein said retainer release trigger (128; 128A) further comprises a locking feature (402) coupled to said trigger portion.

7. The stent-graft delivery system of Claim 6 wherein said locking feature secures said trigger portion to said sheath during use of said stent-graft delivery system.

8. The stent-graft delivery system of any of the preceding claims wherein said retainer structure comprises at least one hook extending from said lumen through at least one corresponding retainer aperture of said pushrod.

9. The stent-graft delivery system of Claim 8 wherein a proximal end of said retainer structure (122; 122A)

- is coupled to said retainer release trigger (128; 128A) by a trigger wire coupler (126).
10. The stent-graft delivery system of any of claims 8 to 9 wherein said at least one hook extends distally from said trigger wire coupler through said at least one corresponding retainer aperture and curves to extend back in the proximal direction.
 11. The stent-graft delivery system of any of claims 8 to 10 further comprising a stent-graft, wherein said at least one hook extends over a portion of said stent-graft (108).
 12. The stent-graft delivery system of Claim 11 wherein said portion of said stent-graft comprises a crown portion (118) of said stent-graft.
 13. The stent-graft delivery system of any of claims 11 to 12 wherein said at least one hook secures said portion of said stent-graft to said pushrod.
 14. The stent-graft delivery system of any of claims 1 to 13 wherein said sheath (112) radially constrains said stent-graft.
 15. The stent-graft delivery system of any of claims 1 to 14 wherein said pushrod (106; 106A) comprises at least one trench (500) defined by at least one proximal annular surface, at least one distal annular surface, and at least one longitudinal ring surface of said pushrod, said retainer structure comprising at least one wire extending across said at least one trench.
 16. The stent-graft delivery system of Claim 15 wherein said at least one wire extends distally from said pushrod through a proximal retainer aperture in said at least one proximal annular surface, across said at least one trench, and back into said pushrod through a distal retainer aperture of said at least one distal annular surface.
 17. The stent-graft delivery system of any of claims 15 to 16 wherein said at least one proximal annular surface, said at least one distal annular surface, said at least one longitudinal ring surface and said at least one wire define at least one pocket, said stent-graft delivery system further comprising a stent-graft comprising a portion located in said at least one pocket.
 18. The stent-graft delivery system of any of claims 15 to 17 further comprising at least one swing pivotally attached to said at least one distal annular surface.
 19. A stent-graft retention system comprising:
 - a retainer structure (122; 122A); and
 - a retainer release trigger (128; 128A) coupled to said retainer structure, said retainer release trigger comprising a pull rod portion (130) coupled to a trigger portion.
 20. The stent-graft retention system of Claim 19 further comprising a trigger wire coupler (126) coupling said retainer structure to said retainer release trigger.
 21. The stent-graft retention system of any of claims 19 to 20 wherein said retainer release trigger further comprises a locking feature coupled to said trigger portion.
 22. A method comprising:
 - mounting a stent-graft (108) on a pushrod;
 - radially constraining said stent-graft within a sheath (112);
 - securing a crown portion (118) of said stent-graft to said pushrod with a retainer structure of a stent-graft retention system (110);
 - retracting said sheath to expose said crown portion of said stent-graft; and
 - further retracting said sheath to release said crown portion from said pushrod.
 23. The method of Claim 22 wherein said stent-graft self-expands upon said release of said crown portion from said pushrod.
 24. The method of any of claims 22 to 23 wherein said further retracting comprises contacting a trigger portion of said stent-graft retention system with a trigger trip surface of said sheath.
 25. The method of any of claims 22 to 24 wherein said further retracting further comprises retracting said trigger portion to retract said retainer structure into said pushrod.
 26. The method of any of claims 22 to 25 wherein said retainer structure is retracted to expose said crown portion.
 27. A stent-graft delivery system comprising:
 - a pushrod (106; 106A);
 - a sheath (112) for radially constraining said stent-graft;
 - a means for securing a crown portion of said stent-graft to said pushrod;
 - a means for retracting said sheath to expose said crown portion of said stent-graft; and
 - a means for releasing said crown portion from said pushrod during further retraction of said

sheath.

- 28.** The stent-graft delivery system of claim 27, further comprising:

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a sten-graft (108) mounted on a pushrod (106; 106A).

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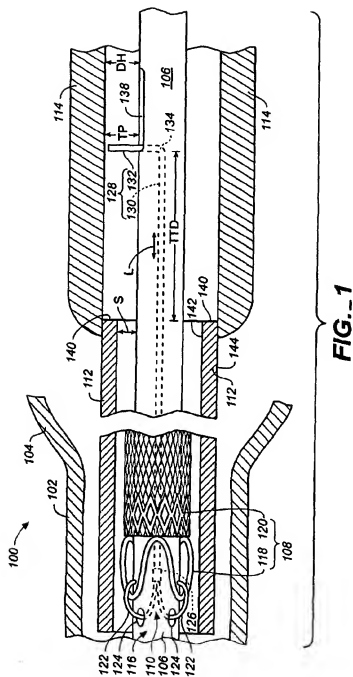
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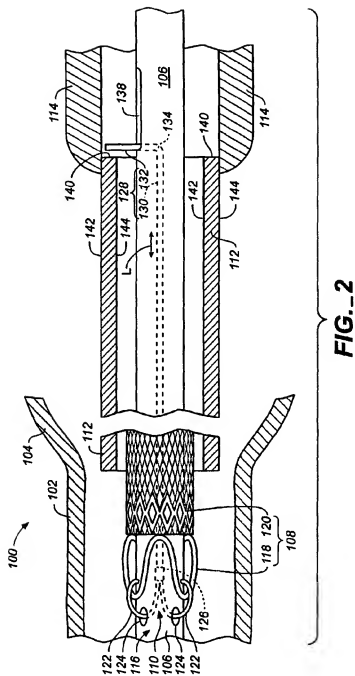
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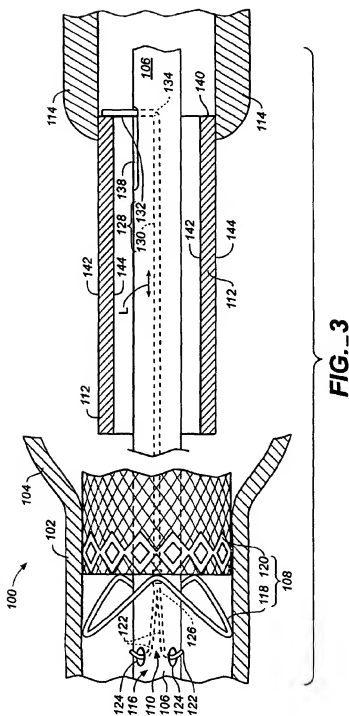
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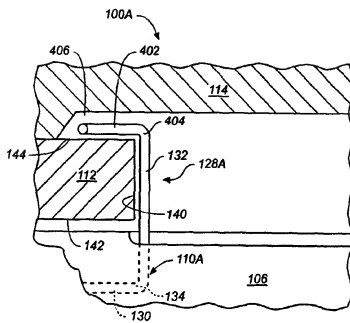


FIG._4

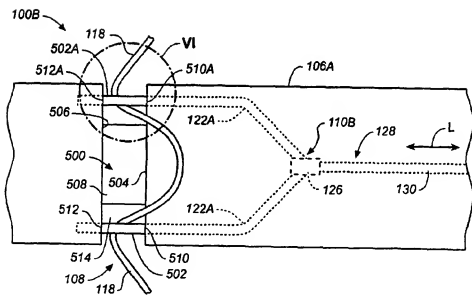
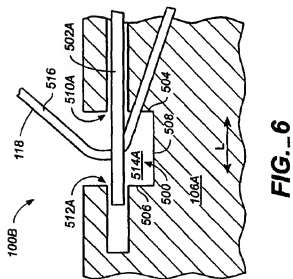
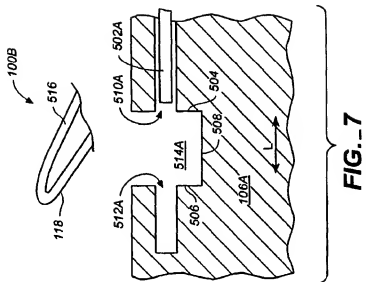
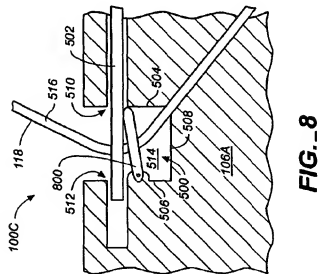
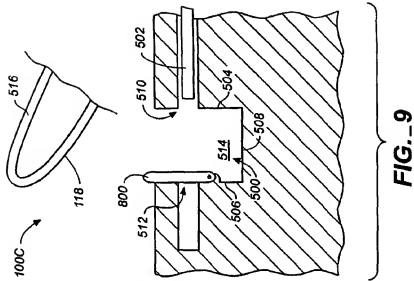


FIG. 5







European Patent
Office

PARTIAL EUROPEAN SEARCH REPORT

Application Number

which under Rule 45 of the European Patent Convention EP 04 00 1463
shall be considered, for the purposes of subsequent
proceedings, as the European search report

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Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
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X A	EP 1 212 989 A (CORDIS CORP) 12 June 2002 (2002-06-12) * figure 15 * * column 13, line 35 - column 14, line 5 * ---	19-21, 27,28 1-18	
X A	WO 96/18361 A (ENDOVASCULAR TECH INC) 20 June 1996 (1996-06-20) * page 7, line 21 - line 28 * * figure 35 * ---	19-21, 27,28 1-18	
		-/-	TECHNICAL FIELDS SEARCHED (Int.Cl.7)
			A61F
INCOMPLETE SEARCH			
<p>The Search Division considers that the present application, or one or more of its claims, does not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for these claims.</p> <p>Claims searched completely</p> <p>Claims searched incompletely:</p> <p>Claims not searched:</p> <p>22-26</p> <p>Reason for the limitation of the search</p> <p>Article 52 (4) EPC - Method for treatment of the human or animal body by surgery</p>			
Place of search		Date of completion of the search	Examiner
MUNICH		5 May 2004	Franz, V
CATEGORY OF CITED DOCUMENTS			
<p>X: particularly relevant if taken alone</p> <p>Y: particularly relevant if combined with another document of the same category</p> <p>A: technological background</p> <p>O: non-written disclosure</p> <p>P: intermediate document</p> <p>T: theory or principle underlying the invention</p> <p>E: earlier patent document, but published on, or after the filing date</p> <p>D: document cited in the application</p> <p>L: document cited for other reasons</p> <p>8: member of the same patent family, corresponding document</p>			

EP01440673A1 (12/02/2004)



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PARTIAL EUROPEAN SEARCH REPORT

Application Number
EP 04 00 1463

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**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 04 00 1463

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on the European Patent Office is in no way liable for these particulars which are merely given for the purpose of information

05-05-2004

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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82



Espacenet

Bibliographic data: EP 1448117 (A1)

ENDOVASCULAR ANEURYSM REPAIR SYSTEM

Publication date: 2004-08-25
Inventor(s): BOLDUC LEE [US] ±
Applicant(s): APTUS ENDOSYSTEMS INC [US] ±
Classification:
 - international: **A61B17/00; A61B17/064; A61B17/068; A61F2/06; A61F2/82; (IPC1-7): A61F2/06**
 - European: **A61B17/064; A61B17/068; A61F2/06P**

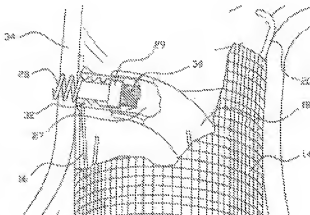
Application number: EP20020789196 20021015
Priority number(s): WO2002US32753 20021015; US2001033937P 20011128; US20020271334 20021015

Also published as:
 • EP 1448117 (A1)
 • WO 03045467 (A2)
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Abstract not available for EP 1448117 (A1) Abstract of corresponding document: WO 03045467 (A2)

Systems and method implant prostheses in the body. The systems and method provide permanent attachment of the prosthesis in the body. The prosthesis can comprise, e.g., an endovascular graft, which can be deployed without damaging the native blood vessel in either an arterial or a venous system. The endovascular graft can comprise, e.g., a radially expanding vascular stent and/or a stent-graft. The graft can be placed in the vasculature, e.g., to exclude or bridge an aneurysm, for example, an abdominal aortic aneurysm. The graft desirably adapts to change in aneurysm morphology and repairs the endovascular aneurysm. The fastening systems (27) and methods can be deployed through the vasculature and manipulated from outside the body, to deliver a fastener (29) to attach the graft to the vessel wall.



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DIALOG(R)File 351: Derwent WPI

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0001238364

WPI Acc no: 1976-L6300X/

Wire attachment element for corrugated cardboard cartons - has corkscrew form with bevelled end and insertion tool with chuck to match

Patent Assignee: MELIN R D (MELI-I)

Patent Family: 1 patents, 1 countries

Patent Number	Kind	Date	Application Number	Kind	Date	Update	Type
FR 2299548	A	19761001	FR 19752979	A	19750130	197649	B

Priority Applications (no., kind, date): FR 19752979 A 19750130

Alerting Abstract FR A

Firm joints in corrugated cardboard cartons are possible with this form of wire screw. The wire (1) is made in the form of a corkscrew with one end (4) bevelled to aid penetration and the other formed into a ring head (2) with a radial portion (6). The radial portion and ring head are so formed to match an insertion tool chuck. Radial slots in the chuck accept and apply torque to the radial part (6) of the wire and an annular rebate centres the wire in the chuck. The chuck itself is driven axially within a cylinder by a coarse thread screw connected via balls to an air driven ram and made to rotate by the fixed nut.

Basic Derwent Week: 197649

Ended session: 2011/02/01 17:27:28

A1

**DEMANDE
DE BREVET D'INVENTION**

(21)

N° 75 02979

(54)

Agrafe, ainsi que le dispositif pour sa mise en place.

(51)

Classification internationale (Int. Cl.⁷).**F 16 B 15/00.**

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Titulaire : *Idem* (71)

(74)

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L'invention concerne une agrafe, ainsi que le dispositif pour sa mise en place.

De plus en plus, actuellement, on tend à remplacer les emballages destinés à contenir des objets lourds ou volumineux et réalisés en bois, par des emballages en carton dont chaque paroi est constituée de plusieurs feuilles de carton, assemblées les unes aux autres par collage, éventuellement avec interposition de carton ondulé.

Les parois épaisses de ces emballages sont alors assemblées les unes aux autres à l'aide de vis et écrous, qui sont disposés au travers de perforations réalisées, à cet effet, en regard l'une de l'autre dans les panneaux à assembler.

Cependant, un tel procédé d'assemblage est onéreux, en raison tout d'abord du prix de revient de chaque vis et écrou, ainsi que des rondelles, qu'il est nécessaire de placer aux extrémités de la vis. Egalement, ce procédé d'assemblage est long, étant donné les perforations qu'il est tout d'abord nécessaire de réaliser dans les cartons, du fait du soin qu'on doit prendre pour maintenir en position les cartons ainsi perforés lors de la mise en place de la vis, et étant donné, enfin, le temps nécessaire au serrage des écrous de ces vis, d'autant plus que ces écrous sont le plus souvent disposés à l'intérieur de l'emballage, à proximité des angles, c'est-à-dire en des endroits peu accessibles.

La présente invention a notamment pour but de remédier à ces inconvénients et concerne, à cet effet, une agrafe caractérisée en ce qu'elle se compose d'au moins une tige métallique rigide tire-bouchonnée dont l'axe détermine le sens de pénétration dans les pièces à assembler, l'une des extrémités du fil étant biseautée, l'autre étant solidaire d'une tête de manoeuvre.

Suivant une autre caractéristique de l'invention, la tête de manoeuvre est formée par pliage du fil lui-même.

Suivant une autre caractéristique de l'invention, l'extrémité du fil plié pour former la tête de manoeuvre présente au moins une portion perpendiculaire à l'axe de la partie du fil tire-bouchonnée.

L'invention concerne également un dispositif pour la mise en place de ce procédé, caractérisé en ce qu'il comporte une vis mobile axialement par vissage dans un écrou fixe, des moyens étant prévus à l'une des extrémités de cette vis pour l'accrochage d'une agrafe.

Suivant une autre caractéristique de l'invention, l'écrou fixe est solidaire d'un corps formant, d'un côté de l'écrou, un manchon pourvu d'un orifice axial recevant l'extrémité de la vis pourvue des moyens d'accrochage de l'agrafe, le diamètre de cet orifice correspondant au diamètre de la tête de l'agrafe.

L'invention est représentée, à titre d'exemples non limitatifs, sur les dessins ci-joints, dans lesquels :

- la figure 1 est une vue en perspective d'un premier mode de réalisation de l'agrafe ;
- la figure 2 est une vue en perspective d'un autre mode de réalisation de cette agrafe ;
- la figure 3 est une vue en coupe axiale du dispositif d'agrafage conforme à l'invention ;
- la figure 4 est une vue en perspective et à échelle agrandie de la tête d'accrochage d'une agrafe dans le dispositif de la figure 3.

L'agrafe conforme à l'invention se compose essentiellement (voir notamment figure 1) d'une partie 1, réalisée à l'aide d'une tige métallique rigide tire-bouchonnée, et d'une tête 2 qui constitue, d'une part, l'organe de manoeuvre de l'agrafe lors de sa mise en place, d'autre part, une surface de butée coopérant avec la partie tire-bouchonnée 1, pour maintenir fermement l'une contre l'autre les deux pièces assemblées.

Ces pièces assemblées seront de préférence constituées par des cartons relativement épais, et notamment par les parois en carton d'emballage, mais il est bien entendu que ces agrafes pourront être utilisées pour l'assemblage de panneaux en tout autre matériau, la rigidité de l'agrafe elle-même devant seulement être fonction de la difficulté de pénétration de l'agrafe dans les panneaux à assembler.

Par ailleurs, par l'expression "partie tire-

bouchonnée" de la tige métallique, on entend une tige métallique enroulée en hélice et dont les pas consécutifs ne sont pas reliés les uns aux autres suivant l'axe 3, ce qui différencie cette partie tire-bouchonnée d'une vis. De préférence, le diamètre de la partie tire-bouchonnée est plusieurs fois supérieur, par exemple dix fois, au diamètre de la tige métallique utilisée. Egalement, dans l'exemple représenté cette tige métallique présente une section circulaire, mais toute autre forme pourra être prévue, étant entendu que la mise en oeuvre d'un fil d'acier à section circulaire permet une fabrication plus simple de l'agrafe.

Conformément à l'invention, cette agrafe présente une partie biseautée à l'extrémité 4 de la partie tire-bouchonnée 1, afin de permettre sa pénétration dans les pièces à assembler, tandis que l'autre extrémité 5 de la partie tire-bouchonnée présente, à hauteur de la tête 2, une portion 6 perpendiculaire à l'axe 3 de la partie tire-bouchonnée, cette partie pliée 6 constituant essentiellement le moyen d'entraînement en rotation de l'agrafe lors de son vissage dans les panneaux à assembler.

Dans l'exemple représenté sur la figure 1, la tête 2 de l'agrafe est réalisée en totalité par la tige métallique elle-même constituant la partie tire-bouchonnée, et, à cet effet, à hauteur de la tête 2, elle est cintrée en forme d'anneau, afin de définir un plan perpendiculaire à l'axe 3 de l'agrafe.

Dans l'exemple de réalisation de la figure 3, on a représenté une agrafe dont la partie tire-bouchonnée est réalisée à l'aide de deux tiges métalliques 7 et 8, enroulées coaxialement en hélice, et dont les extrémités 7₁ et 8₁ sont biseautées ou pointues.

Dans cet exemple, la tête de l'agrafe est constituée par une plaque métallique 9, soudée en 10 aux deux extrémités des tiges métalliques 7 et 8, cette plaque métallique 9 présentant des rebords ou nervures 11 pour l'actionnement manuel, ou à l'aide d'un outil, de cette agrafe, pour sa mise en place.

Ces agrafes pourront être mises en place pour l'assemblage de panneaux, à l'aide d'un dispositif tel

que celui représenté sur les figures 3 et 4, qui est particulièrement destiné à la mise en place d'agrafes telles que celles représentées sur la figure 1.

5 Ce dispositif se compose d'une vis 12, placée dans un écrou fixe 13, cette vis étant pourvue, à l'une de ses extrémités, d'une tête 14 sur laquelle est destinée à s'accrocher la tête 2 de l'agrafe, pour sa mise en place. A cet effet, cette tête 14 comporte des fentes diamétrales 15, par exemple au nombre de deux, dans l'une
10 desquelles est destinée à venir se loger la partie 6 de l'agrafe. Egalement, cette extrémité de la tête 14 comporte des plans 16, inclinés dans le même sens que les filets de la vis 12, de manière à favoriser l'accrochage de la partie 6 dans les fentes 15.

15 En outre, la périphérie de cette extrémité de la tête forme une rainure annulaire 17 dont le diamètre correspond au diamètre intérieur de l'anneau 2, afin que cet anneau puisse venir se placer dans cette rainure 17, pour coopérer ainsi au centrage de l'agrafe.

20 Comme on le remarque sur la figure 4, cette rainure annulaire 17 présente également des plans inclinés 18 à proximité de l'extrémité des fentes diamétrales 15, ces plans inclinés étant destinés à recevoir la partie coudée de la tige métallique, à hauteur de la jonction de la partie 6
25 et de l'anneau 2, afin de tenir compte des défauts éventuels de planéité de la tête en cet endroit.

L'écrou 13, recevant la vis 12, est lui-même fixé par vissage à l'intérieur d'un corps qui, dans l'exemple représenté, est réalisé en deux parties 19 et 20, assemblées
30 par vissage sur cet écrou 13. La partie 20 du corps comporte un orifice axial 21 dont le diamètre correspond sensiblement au diamètre de la tête 2 de l'agrafe et qui reçoit l'extrémité de la vis 12 pourvue de la tête 14.

Par ailleurs, la partie 19 du corps comporte
35 un orifice axial 22, dans lequel peut se déplacer une pièce 23 montée à rotation à l'extrémité de la vis 12. Cette pièce 23 est montée à rotation à l'extrémité de la vis 12 par l'intermédiaire de billes 24 maintenues dans un logement formé entre le fond de la pièce 23 et un écrou 25 fixé à
40 l'extrémité du corps de la vis 12.

Le dispositif de l'invention représenté sur la figure 3 est destiné à s'adapter sur un organe de manoeuvre, et particulièrement sur un pistolet pneumatique produisant le déplacement axial de la vis 12 par vissage dans l'écrou 13, pour l'enfoncement par vissage de l'agrafe dans les panneaux à assembler.

A cet effet, la partie 19 du corps comporte une collerette 26 destinée à s'accrocher sur des moyens 27 prévus à cet effet sur le pistolet pneumatique, tandis que la pièce 23 est pourvue d'un filetage intérieur pour recevoir le mandrin 28 de manoeuvre du pistolet pneumatique. La force de pression du mandrin 28 s'exerce sur la vis 12, par l'intermédiaire d'une bille en acier 29 centrée dans l'axe de cette vis 12 par une pièce de forme 30.

Ainsi, lors de l'actionnement du pistolet automatique, le mandrin 28 se déplace axialement, afin d'exercer, par l'intermédiaire de la bille 29, une pression axiale sur la vis 12 qui tend alors à se visser dans l'écrou 13, afin que la tête 14 s'accroche sur la tête 2 de l'agrafe préalablement disposée dans l'orifice axial 21.

Dans cette construction, évidemment, le pas de la vis 12 correspond au pas de la partie tire-bouchonnée 1 de l'agrafe.

Bien entendu, l'invention n'est pas limitée aux exemples de réalisation ci-dessus décrits et représentés, à partir desquels on pourra prévoir d'autres modes et d'autres formes de réalisation, sans pour cela sortir du cadre de l'invention.

RE V E N D I C A T I O N S

1°/ Agrafe caractérisée en ce qu'elle se compose d'au moins une tige métallique rigide tire-bouchonnée dont l'axe détermine le sens de pénétration dans les pièces
5 à assembler, l'une des extrémités du fil étant biseautée, l'autre étant solidaire d'une tête de manoeuvre.

2°/ Agrafe conforme à la revendication 1, caractérisée en ce que la tête de manoeuvre est formée par pliage du fil lui-même.

10 3°/ Agrafe conforme à la revendication 2, caractérisée en ce que l'extrémité du fil plié pour former la tête de manoeuvre présente au moins une portion perpendiculaire à l'axe de la partie du fil tire-bouchonnée.

15 4°/ Agrafe conforme à l'une quelconque des revendications 1 à 3, caractérisée en ce que le fil rigide, pour constituer la tête de l'agrafe, est cintré à la forme d'un anneau définissant un plan perpendiculaire à l'axe de la partie du fil tire-bouchonnée.

20 5°/ Agrafe conforme à la revendication 1, caractérisée en ce que la tête de l'agrafe est constituée d'une plaque métallique soudée perpendiculairement à l'extrémité de la partie tire-bouchonnée, cette plaque étant pourvue de nervures de préhension.

25 6°/ Agrafe conforme à l'une quelconque des revendications 1 à 5, caractérisée en ce qu'elle est réalisée en fil d'acier à section circulaire.

30 7°/ Dispositif pour la mise en place de l'agrafe conforme à l'une quelconque des revendications 1 à 6, caractérisé en ce qu'il comporte une vis mobile axialement par vissage dans un écrou fixe, des moyens étant prévus à l'une des extrémités de cette vis pour l'accrochage d'une agrafe.

35 8°/ Dispositif conforme à la revendication 6, caractérisé en ce que l'écrou fixe est solidaire d'un corps formant, d'un côté de l'écrou, un manchon pourvu d'un orifice axial recevant l'extrémité de la vis pourvue des moyens d'accrochage de l'agrafe, le diamètre de cet orifice correspondant au diamètre de la tête de l'agrafe.

40 9°/ Dispositif conforme à la revendication 8, caractérisé en ce que le corps forme, de l'autre côté de

l'écrou, un manchon creux recevant l'autre extrémité de la vis, cette extrémité de la vis étant pourvue de moyens pour son accrochage à des moyens assurant son vissage dans l'écrou.

5 10°/ Dispositif conforme à la revendication 9, caractérisé en ce que les moyens prévus à l'extrémité de la vis et assurant son accrochage à des moyens de commande de son vissage, sont constitués par une pièce montée à rotation sur cette extrémité de la vis.

10 11°/ Dispositif conforme à la revendication 9, caractérisé en ce que la pièce montée à rotation à l'extrémité de la vis comporte au moins une bielle en acier, appliquée contre l'extrémité de la vis.

15 12°/ Dispositif conforme à la revendication 9, caractérisé en ce que le corps comporte des moyens pour sa fixation sur un pistolet pneumatique, et la pièce montée à rotation à l'extrémité de la vis comporte des moyens pour sa liaison à la tige de manoeuvre du pistolet, ces moyens assurant l'application de l'extrémité de la tige de manoeuvre contre la bille appliquée sur l'extrémité de la vis.

20

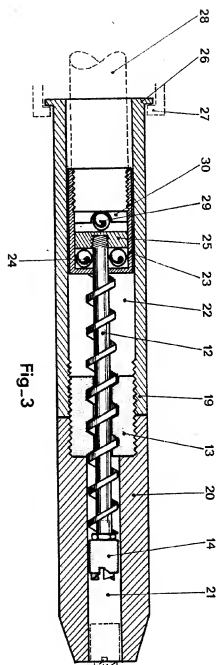


Fig-3

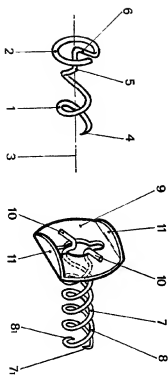


Fig-1

Fig-2

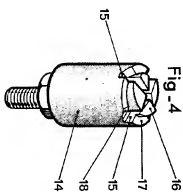


Fig-4

A PROSTHESIS AND A METHOD AND MEANS OF DEPLOYING A PROSTHESIS

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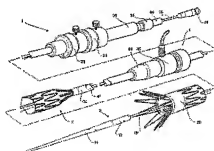
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more >>

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An introducer (1) adapted for the introduction of a self-expanding endovascular prosthesis (20) in a lumen of a patient. The introducer has attachment devices (10, 30) to hold each end of the prosthesis so that each can be moved independently. An end ovascular prosthesis (20) is also claimed with stents at the proximal and distal ends being within the graft. The remainder of the stents are positioned on the outside of the graft body.



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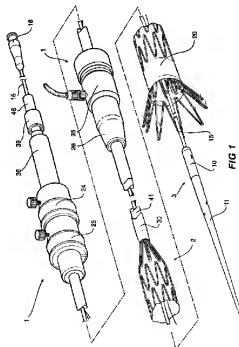
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(54) 【発明の名称】 プロテーゼ及び該プロテーゼを配置する方法及び手段

(57) 【要約】

患者の管腔内に、自己膨張性の血管内膜プロテーゼ (20) を挿入することができる誘導針 (1)。この誘導針は、プロテーゼの各端部を保持するための取付器具 (10, 30) を有し、これにより、各端部をそれぞれ独立に移動させることができる。血管内膜プロテーゼ (20) は、グラフト内に存在する近位端部及び遠位端部にステントも有する。ステントの残余部分はグラフト本体の外側に配置される。



【特許請求の範囲】

1. 膨張性血管内膜プロテーゼ(20)を患者の管腔に配置する誘導針であって、プロテーゼは近位部分および遠位部分を有し、誘導針が、プロテーゼが患者の管腔の所望の部位に配置されるとプロテーゼから選択的に解放できるプロテーゼ配置機構(2、3)と、プロテーゼの近位部分の少なくとも縦方向の位置を制御する第1の制御部材(22、24)と、プロテーゼの遠位部分の少なくとも縦方向の位置を制御する第2の制御部材(44、25)とを備えることを特徴とする誘導針。

2. 前記プロテーゼ配置機構が遠位取付領域(2)および／または近位取付領域(3)を含むことを特徴とする請求項1に記載の誘導針。

3. 前記遠位取付領域が遠位取付器具(10)を含むことを特徴とする請求項2に記載の誘導針。

4. 前記近位取付領域が近位取付器具(10)を含むことを特徴とする請求項2または3に記載の誘導針。

5. プロテーゼ配置機構が、プロテーゼの長さを制御する制御装置(15、41)を有することを特徴とする請求項1から4のいずれかに記載の誘導針。

6. プロテーゼ配置機構が、プロテーゼの近位および遠位部分の相対的角方向を調節することができる回転装置(15、41)を備えることを特徴とする請求項1から4のいずれかに記載の誘導針。

7. プロテーゼ配置機構が、プロテーゼの角方向を調節することができる回転装置(15、41)を有することを特徴とする請求項1から4のいずれかに記載の誘導針。

8. 誘導針が、プロテーゼが患者の管腔の所望の部位に配置されると、プロテーゼの膨張を制御する膨張制御機構(10、30)をさらに有することを特徴とする請求項1から7のいずれかに記載の誘導針。

9. 患者の管腔の所望の位置に膨張性プロテーゼを配置する血管内膜装置であって、

前記装置が、

患者の体外に維持される制御区間（１）と、

管腔の所望の位置にプロテアーゼを移動させ、これ进行操作するために制御区間によって制御可能なプロテアーゼ配置機構（２、３）とを有し、

第１の部材（１５）が制御区間から配置機構の近位領域（３）へと延在し、配置機構の近位領域がプロテアーゼの近端を制御する手段（１０）を有し、

第２の部材（４１）が制御区間から配置機構の遠位領域（２）へと延在し、遠位領域が第２の部材と協力してプロテアーゼの遠端を制御する手段（４０）を有することを特徴とする血管内膜装置。

１０． 前記装置が、プロテアーゼ配置機構を管腔に挿入する間にプロテアーゼの自己膨張性ステントを含む後退手段および／またはプロテアーゼが患者の管腔の所望の部位に配置されると、プロテアーゼの膨張性ステントを膨張させる膨張手段を更に有することを特徴とする請求項９に記載の血管内膜装置。

１１． 後退手段が、制御区間から配置機構まで延在して、配置機構を管腔に挿入する間にプロテアーゼを含み、管状手段を第１および第２の部材に対して遠位方向に移動させた時に、プロテアーゼの遠端を制御する働きをする管状手段（３０）を有し、第１の部材と第２の部材間の相対運動によって、プロテアーゼが管腔内にある時にこれ进行操作できることを特徴とする請求項１０に記載の装置。

１２． 前記膨張手段が、プロテアーゼが管腔の所望の位置に配置された時にプロテアーゼのステントを半径方向に膨張可能な、少なくともラジアル手段を有することを特徴とする請求項１０または１１に記載の装置。

１３． 前記膨張手段が膨張可能なバルーンを有することを特徴とする請求項１２に記載の装置。

１４． 第１および第２の部材が前記管状手段の中に含まれることを特徴とする請求項１２に記載の装置。

１５． 手段（３９）が、プロテアーゼの挿入中に第１の部材と第２の部材とを合わせて締め付け、操作する前に第１および第２の部材を解放するため設けられることを特徴とする請求項１２または１４に記載の装置。

１６． 非自己膨張性プロテアーゼの膨張が、第１の部材の周囲でプロテアーゼの中に配置されたバルーンの膨張によって実行することができ、前記バルーンが制

御区間から膨張可能であることを特徴とする請求項12、14または15に記載の装置。

17. 取付機構の前記近位領域が、プロテーゼを最終的に配置する前にその近端を含む管状手段(10)を含み、プロテーゼの管状手段(10)からの解放が、第1の部材の近位方向への運動によって達成されることを特徴とする請求項12、14、15または16に記載の装置。

18. 前記第2の部材が、ステントの遠端が管状手段(30)の内側にある間、これを制御する手段(40)を有することを特徴とする請求項9から17のいずれかに記載の装置。

19. 前記装置が、プロテーゼの個々のステントへと延在する線(22、44)を制御するため、制御区間内に解放機構(24、25)を更に有することを特徴とする請求項9から18いずれか一項に記載の装置。

20. 前記プロテーゼ配置機構がプロテーゼの長さを制御する制御装置(15、41)を有することを特徴とする請求項9から19のいずれかに記載の装置。

21. 前記プロテーゼ配置機構が、プロテーゼの近位および遠位部分の相対的角度方向を調節することができる回転装置(15、41)を有することを特徴とする請求項9から19のいずれかに記載の装置。

22. 前記プロテーゼ配置機構が、プロテーゼの角度方向を調節することができる回転装置(15、41)を有することを特徴とする請求項9から19のいずれかに記載の装置。

23. 前記誘導針が、プロテーゼが患者の管腔の所望の部位に配置されると、プロテーゼの膨張を制御する膨張制御機構(10、30)を更に有することを特徴とする請求項9から19のいずれかに記載の装置。

24. 自己膨張性血管内膜プロテーゼを患者の管腔に誘導するようになっている誘導針であって、プロテーゼが近端および遠端を有し、誘導針が、

- a. プロテーゼの近端に取り付けるようになっている近位取付器具と、
- b. プロテーゼの遠端に取り付けるようになっている遠位取付器具と、
- c. プロテーゼの間に張力をかけてこれを保持することができ、プロテ

ーゼの各端を個々に近位および遠位方向に移動し、回転することができるような方法でプロテーゼに取り付けられる近位および遠位取付器具それぞれと、

d. プロテーゼの近端および遠端を選択的に解放できるよう、近位取付器具に関連した近位解放手段と、遠位取付器具に関連した遠位解放手段とを有することを特徴とする誘導針。

25. 前記近位取付手段が、近端に長い可撓性延長部を有し、誘導針の体内への挿入および管腔に沿った前進を容易にすることを特徴とする請求項24に記載の誘導針。

26. 前記近位取付器具が、近位取付器具から患者の体外に残るようになっている誘導針の外部操作区間まで遠位方向に延在する可撓性肉厚管に装着されることを特徴とする請求項25に記載の誘導針。

27. 肉薄金属管が、患者の体外に流体接続手段を有し、医薬品を誘導できることを特徴とする請求項26に記載の誘導針。

28. 長い可撓性延長部が、肉薄金属管と流体連絡する中空の管と、プロテーゼの近位側で医薬品を分散できる複数の側穴とを有することを特徴とする請求項27に記載の誘導針。

29. 遠位取付器具が、可撓性肉厚管に装着され、肉薄管と同軸上にあり、外部操作区間まで遠位方向に延在し、個々の管を一緒に移動するか、別個に移動できるように装着されることを特徴とする請求項26に記載の誘導針。

30. 操作区間の肉薄管と肉厚管の間に止血シールを有することを特徴とする請求項29に記載の誘導針。

31. 医薬品を、肉薄管と肉厚管の間に規定された環状空間に誘導する手段を有することを特徴とする請求項30に記載の誘導針。

32. 近位取付器具から操作区間へと延在する近位トリガー線を含み、近位トリガー線が近位解放手段を起動するようになっていることを特徴とする請求項24に記載の誘導針。

33. 遠位取付器具から操作区間へと延在する遠位トリガー線を含み、遠位トリガー線が遠位解放手段を起動するようになっていることを特徴とする請求項24に記載の誘導針。

34. 近位トリガー線および遠位トリガー線のそれぞれの外部解放機構を含み、外部解放機構が、トリガー線の偶発的な解放を防止し、近位解放手段の解放後にのみ遠位解放手段を解放できるようになっていることを特徴とする請求項24に記載の誘導針。

35. 操作区間の個々のトリガー線の周囲に止血シールを有することを特徴とする請求項34に記載の誘導針。

36. 患者の体外から延在し、誘導針を患者に誘導する間にプロテーゼを覆って、これを圧縮し、患者の体外から縦方向に移動してプロテーゼを露出できる外鞘を有することを特徴とする請求項24に記載の誘導針。

37. 外鞘が肉厚管と同軸上にあり、それと滑り嵌めすることを特徴とする請求項36に記載の誘導針。

38. 外鞘が、先細で、平滑にされ、挿入中に誘導針の前進に対して抵抗が少ない近端を有することを特徴とする請求項37に記載の誘導針。

39. 外鞘の近端が、近位取付器具に締められるようになっていることを特徴とする請求項36に記載の誘導針。

40. 遠位取付器具が流線形であり、近位取付器具へと前進するようになっていて、それにより患者から取り外すために解放されたプロテーゼを通して外鞘へと滑らかに後退できることを特徴とする請求項24に記載の誘導針。

41. プロテーゼが二又プロテーゼであることを特徴とする請求項24に記載の誘導針。

42. 患者の管腔が動脈であり、プロテーゼが大動脈瘤を治療するようになっていることを特徴とする請求項1から41のいずれかに記載の誘導針。

43. 挿入アセンブリによってプロテーゼを体内管腔に配置する方法であって、

(a) プロテーゼを含む挿入アセンブリを体内管腔に挿入するステップと、

(b) 挿入アセンブリから鞘を引き抜いてプロテーゼを露出させるステップと、

(c) 挿入アセンブリからプロテーゼを解放するステップと、

(d) 鞘を挿入アセンブリ上に戻すステップと、

(e) 挿入アセンブリを後退させるステップと、

を含むことを特徴とする方法。

44. プロテゼが近端および遠端を有し、挿入アセンブリが、プロテゼの近端および遠端をそれぞれ保持するようになっている近位取付器具および遠位取付器具を含み、プロテゼを解放するステップが、近端を解放してから遠端を解放するステップを含むことを特徴とする請求項43に記載の方法。

45. 鞘を挿入アセンブリ上に戻すステップが、遠位取付器具を近位取付器具まで前進させ、2つの器具と一緒に引き抜くステップを含むことを特徴とする請求項44に記載の方法。

46. ステップ(b)と(c)との間で、プロテゼが近位取付器具および遠位取付器具のそれぞれの運動によって操作され、プロテゼを正確に配置することを特徴とする請求項44に記載の方法。

47. プロテゼが二又プロテゼであり、鞘を引き抜くステップが、プロテゼのサイド・アームが露出する第1の位置へと鞘を引き抜くステップと、延長プロテゼをサイド・アームに挿入するステップと、次に鞘をプロテゼから完全に外すステップとを含むことを特徴とする請求項43に記載の方法。

48. 延長プロテゼをサイド・アームに挿入するステップが、

(f) 延長挿入アセンブリをサイド・アームに挿入するステップを含み、前記延長挿入アセンブリが、カテーテルに装着された頂部ガイドと、カテーテル上の延長プロテゼと、延長プロテゼを保持して頂部ガイド上に延在する鞘とを有し、さらに、

(g) 鞘を引き抜いて延長プロテゼを露出させ、配置するステップと、

(h) 鞘、頂部ガイドおよびカテーテルと一緒に引き抜くステップとを有することを特徴とする請求項47に記載の方法。

49. 頂部ガイドが長い近位ノーズ延長部を有することを特徴とする請求項48に記載の方法。

50. カテーテルが遠位止め具を有し、延長プロテゼが遠位止め具と頂部

ガイドとの間に装着されることを特徴とする請求項48に記載の方法。

51. プロテレーゼが二又プロテレーゼであり、鞘を引き抜くステップが、プロテレーゼの第1のサイド・アームが露出する第1の位置へと鞘を引き抜くステップと、第1の延長プロテレーゼを第1のサイド・アームに挿入するステップと、鞘をプロテレーゼから完全に外して第2のサイド・アームを露出させるステップと、次に第2の延長プロテレーゼを第2のサイド・アームに挿入するステップを含むことを特徴とする請求項43に記載の方法。

52. 第1の延長プロテレーゼをサイド・アームに挿入するステップが、
(f) 第1の延長挿入アセンブリを第1のサイド・アームに挿入するステップを含み、第1の延長挿入アセンブリが、カテーテルに装着された頂部ガイドと、カテーテル上の延長プロテレーゼと、延長プロテレーゼを保持して頂部ガイド上に延在する鞘とを含み、さらに、

(g) 鞘を引き抜いて延長プロテレーゼを露出させ、配置するステップと

、
(h) 鞘、頂部ガイドおよびカテーテルを一緒に引き抜くステップとを含み、

第2の延長アームを挿入するステップが、

(i) 第2延長挿入アセンブリを第2サイド・アームに挿入するステップを有し、第2の延長挿入アセンブリが、カテーテルに装着された頂部ガイドと、カテーテル上の延長プロテレーゼと、延長プロテレーゼを保持して頂部ガイド上に延在する鞘とを有し、さらに、

(j) 鞘を引き抜いて延長プロテレーゼを露出させ、配置するステップと

、
(k) 鞘、頂部ガイドおよびカテーテルを一緒に引き抜くステップと、を有することを特徴とする請求項51に記載の方法。

53. 頂部ガイドがそれぞれ長い近位ノーズ延長部を有することを特徴とする請求項52に記載の方法。

54. カテーテルがそれぞれ遠位止め具を有し、延長プロテレーゼが遠位止め具と頂部ガイドとの間に装着されることを特徴とする請求項52に記載の方法。

63. 各ステントがジグザグ形ステントであることを特徴とする請求項55に記載の管内プロテーゼ。

【発明の詳細な説明】発明の名称

プロテーゼ及び該プロテーゼを配置する方法及び手段

発明の詳細な説明技術分野

本発明は、直線状、管状または二又状の形状で、罹患または損傷脈管の血管内膜治療を意図した膨張性管内プロテーゼ（人工器官）を誘導する方法および手段、およびこのような処置に適したプロテーゼに関する。

この明細書の全体を通して使用される、「近位」及び「近位に」という用語は、患者の心臓に近い位置または方向を意味し、「遠位」及び「遠位に」という用語は、患者の心臓から遠い位置または方向を意味する。

背景技術

配置器具または誘導針の使用による遠隔位置から患者の管腔への管内プロテーゼの配置が、従来の幾つかの特許明細書に記載されている。

米国特許第4562596号明細書には、スリーブを引き込み、グラフトが膨張可能になる時点で配置するまで、スリーブ内に自己膨張式グラフトを保持することが記載されている。グラフトの解放後には、グラフトの遠端位置の制御は不可能である。不適切な配置により、配置全体が無意味で無効になることがある。

米国特許第4665918号明細書には、血管内にプロテーゼを配置するシステムおよび方法が記載されている。プロテーゼは送出力カテーテルと外鞘との間に配置され、鞘を外すと外側に膨張する。この場合も、鞘を外してプロテーゼを解放すると、プロテーゼのいずれかの端の位置を制御することは不可能である。

米国特許第4950227号明細書には、ステントを膨張性カテーテルの外側に装着し、ステントのいずれかの端にスリーブを被せることにより、拡張していないステントの端を保持するステントの送出が記載されている。ステントの拡張は、ステントの端を個々のスリーブから引き出し、ステントを解放して所定の位置に拡張するよう、スリーブ間でカテーテルを膨張させて実行する。このシステムは、配置手順をほとんど制御できず、実際面では、正確さが非常に重要な管内配置には非実用的となる。

欧州特許第472731号明細書には、カテーテル内に保持され畳んだ状態で人体器官内に挿入され、期間内で膨張するよう解放される人工管プロテーゼが記載されている。配置は、カテーテルを取り出しながら、管を通してプロテーゼの中央を通る線によってプロテーゼの近端を保持することによって達成される。次に、バルーンを使用してプロテーゼを膨張させる。この場合も、カテーテルを外してプロテーゼを解放した後、プロテーゼの遠端の位置を制御することが不可能である。

米国特許第5071407号明細書には、カテーテルと鞘の間に弾性変形する状態のステントを保持したステントの送出が記載されている。ステントの近端は、カテーテルで保持される。ステントは、鞘を外し、任意選択のバルーンを膨張させることによって、拡張することができる。カテーテルからステントを解放する方法、またはステントの遠端を正確に配置できる方法についての記載はない。

オーストラリア特許第669338号明細書には、管腔の内壁の特定位置にプロテーゼを経腔的に配置する送出装置が記載されている。送出装置は、プロテーゼを囲む外鞘と、最終的な解放の前に鞘を外す間、プロテーゼを選択位置で保持する保持装置とを有する。

オーストラリア特許第671910号明細書には、管腔内にプロテーゼを配置する送出装置が記載されている。これはプロテーゼの各端を保持するカプセルと、カプセルを後退させてプロテーゼを解放した時にプロテーゼを膨張させるバルーン装置とを有する。鞘を使用して、挿入中にプロテーゼを保護する。カプセルを引き出すと、プロテーゼの端が正確に配置されていることを保証する方法がない。

グラフトを提供し、上記の問題の少なくとも幾つかを克服するか、少なくとも上述した先行技術のシステムの代替装置を提供するグラフト・プロテーゼを配置する方法および装置を提供することが、本発明の目的である。

発明の開示

本発明の或る実施態様によれば、患者の管腔に膨張性血管内膜プロテーゼを配置する誘導針が提供される。このプロテーゼは近位部分および遠位部分を有し、誘導針は、プロテーゼが患者の管腔の所望の部位に配置されると、プロテ

ーゼから選択的に解放可能なプロテーゼ配置機構と、プロテーゼの近位部分の少なくとも縦方向位置を制御する第1の制御部材と、プロテーゼの遠位部分の少なくとも縦方向位置を制御する第2の制御部材とを備える。プロテーゼ配置機構は、遠位取付領域および／または近位取付領域を含むことができる。遠位取付領域は、遠位取付器具を含むことができる。近位取付領域は、近位取付器具を含むことができる。プロテーゼ配置機構は、好ましくは、プロテーゼの長さを制御する制御装置を含むことができる。プロテーゼ配置機構は、好ましくはプロテーゼの近位および遠位部分の相対的角度方向を調節することができる回転装置も含むことができる。このプロテーゼ配置機構は、単独で、または組み合わせてプロテーゼの角度方向を調節することもできる。誘導針は、好ましくは、プロテーゼが患者の管腔の所望の部位に配置されたら、プロテーゼの膨張を制御する膨張制御機構も備えることができる。

本発明の別の実施態様によれば、患者の管腔の所望の位置に膨張性プロテーゼを配置する血管内膜装置が提供される。前記装置は、患者の外側に維持される制御区間と、プロテーゼを管腔の所望の位置まで移動させ、操作するため、制御区間によって制御可能なプロテーゼ配置機構とを備え、第1の部材が制御区間から配置機構の近位領域まで延在し、配置機構の近位領域が、プロテーゼの近端を制御する手段を有し、第2の部材が、制御区間から配置機構の遠位領域まで延在し、遠位領域は、第2の部材と協力してプロテーゼの遠端を制御する手段を有する。装置はさらに、プロテーゼを患者の管腔の所望の部位に配置する場合に、プロテーゼの拡張性ステントを拡張するため、プロテーゼ配置機構を管腔および／または拡張手段に挿入する間、プロテーゼの自己拡張式ステントを含む収縮手段も備えることが好ましい。収縮手段は管状手段を含み、これは、制御区間から配置機構まで延在し、配置機構を管腔に挿入する間、プロテーゼを含み、管状手段が第1および第2の部材に対して遠位方向に移動する時にプロテーゼの遠端を制御する働きをし、第1、第2の部材間の相対的移動により、プロテーゼが管腔内にある時にこれ进行操作できることが好ましい。拡張手段は、プロテーゼが管腔の所望の位置に配置された時に、プロテーゼの半径方向に拡張可能なステント用に、好ましくは膨張性バルーンなどの少なくとも半径方向の部材を含む。第1

および第2の部材は、前記管状手段に含めることができる。手段は、プロテレーゼの挿入中に第1の部材と第2の部材とを互いに締め付け、操作する前に第1および第2の部材を解放するよう設けることができる。非自己膨張性プロテレーゼの膨張は、プロテレーゼ内で第1の部材の周囲に配置されたバルーンを膨張させて実行することができ、前記バルーンは制御区間から膨張させることができる。取付機構の近位領域は、プロテレーゼを最終的に配置する前にその近端を含む管状手段を含むことができ、管状手段からのプロテレーゼの解放は、第1の部材を近位方向に移動させて実行することができる。第2の部材は、ステントが管状手段の内側にある間に、その遠端を制御する手段を有する。装置は、さらに、プロテレーゼの個々のステントへと延在する線を制御するため、制御区間に解放機構を備えることができる。プロテレーゼ配置機構は、好ましくは、プロテレーゼの長さを制御する制御装置を含むことができる。プロテレーゼ配置機構は、好ましくは、プロテレーゼの近位および遠位部分の相対的角度方向を調節できる回転装置も含むことができる。このプロテレーゼ配置機構は、単独で、または組み合わせて、プロテレーゼの角度方向を調節することもできる。誘導針は、プロテレーゼが患者の管腔の所望の部位に配置された時に、プロテレーゼの膨張を制御する膨張制御機構も備えることができる。

上記の誘導針および／または装置を使用して、膨張性プロテレーゼまたは自己膨張性プロテレーゼを配置することができる。前者を使用する場合は、制御区間から、または患者の外側から膨張可能な1つまたは複数のバルーンを使用することができる。

血管内膜装置の第1の部材は、延長部に取り付けることができるか、または部材を実際に延長部の形状に成形することができる。

誘導針の第1および第2の制御部材は、好ましくは単独で、または組み合わせて、プロテレーゼの近および／または遠端に配置されたトリガ線を含むことができる。トリガ線は、好ましくは、プロテレーゼが患者の管腔部位に配置された時に、配置機構からプロテレーゼを解放するため、患者の外側の1つまたは複数の解放機構まで延在することができる。

幾つかの形態の容器または膨張制御機構を使用して、プロテレーゼの残り

の部分患者の管腔内で操作している間、この端を含むことができる。種々の制御部材を操作して容器を取り出すのは、操作を実行した後である。

本発明の別の実施態様では、本発明の誘導針または血管内膜装置は、患者の体内で操作中にプロテーゼの長さを制御する制御装置も備えることができる。一つの実施態様では、制御装置または部材が、好ましくは、プロテーゼを回転させるために、その個々の端に接続された同軸管を含むことができる。制御部材を互いにロックすると、プロテーゼ全体を患者の管腔内で回転することができる。あるいは、制御装置および／または部材を個々に制御して、同方向または反対方向に互いに対してプロテーゼの個々の端を回転することができる。

スリーブは制御装置および／または第1および第2制御部材とは独立して配置することができる。制御装置または部材も、スリーブに含めることができる。スリーブは、好ましくは、管、線の外被、または線を入れた管でもよい。前述したトリガまたは解放線もスリーブ管または管の壁内に含むことができる。

膨張性プロテーゼに関して、プロテーゼの膨張性ステントを膨張させる膨張手段は、好ましくは、プロテーゼの近位および遠位部分、さらにその中間区間を有利がつ独立して膨張させるため、1つまたは複数のバルーン（より好ましくは3つのバルーン）を含むことができる。

別の形態では、本発明は、自己膨張性血管内膜プロテーゼを患者の管腔内に誘導するようになっている誘導針にあるとすることができ、プロテーゼは、近端および遠端を有し、誘導針は、プロテーゼの近端に取り付けるようになっている近位取付器具と、プロテーゼの遠端に取り付けるようになっている遠位取付器具とを備え、近位および遠位取付器具はそれぞれ、プロテーゼの間に張力をかけてこれを保持することができ、プロテーゼの各端を個々に近位および遠位方向に移動し、回転することができるような方法でプロテーゼに取り付けられ、さらに近位取付器具に関連した近位解放手段と、遠位取付器具に関連した遠位解放手段とを有し、プロテーゼの近端および遠端を選択的に解放することができる。

本発明の好ましい形態では、近位取付手段は近端に長く先細の可撓性延長部を有し、体内の管腔への誘導針の挿入、および管腔に沿った前進を容易にする。

近位取付器具は、近位取付器具から患者の体外に残るようになっている誘導針の外部操作区間へと遠位方向に延在する可撓性薄肉管に取り付けてもよい。

金属肉薄管は、患者の体外にある流体接続手段を含み、医薬品の導入を可能にすることができる。

長い可撓性延長部は、金属肉薄管および複数の側穴と流体連絡して、プロテゼの近位側で医薬品の分散を可能にする中空の管を含むことができる。

本発明の好ましい形態では、遠位取付器具が可撓性肉厚管に取り付けられ、肉薄管と同軸であり、外部操作区間へと遠位方向に延在し、それぞれの管と一緒に、または独立して移動できるように取り付けられる。

さらに、操作区間の肉薄管と肉厚管との間に、止血シールを含んでもよい。

さらに、医薬品を薄肉管と肉厚管との間に規定された環状空間に誘導する手段を含んでもよい。

本発明の好ましい形態では、近位取付器具から操作区間へと延在する近位トリガー線があってもよく、近位トリガー線は近位解放手段を起動するようになっており、遠位取付器具から操作区間まで延在する遠位トリガー線があってもよく、遠位トリガー線は遠位解放手段を起動するようになっている。

本発明の好ましい形態では、近位トリガー線と遠位トリガー線のそれぞれの外部解放機構を含んでもよく、外部解放機構は、トリガー線の偶発的な解放を防止し、近位解放手段の解放後のみ遠位解放手段を解放できるようになっている。

操作区間のそれぞれのトリガー線の周囲には、止血シールがあることが好ましい。

誘導針は、患者の体外から延在して、誘導針を患者に挿入する間、プロテゼを覆ってこれを圧迫し、患者の外側から縦方向に移動してプロテゼを露出させることができる外鞘も含んでもよい。

外鞘は肉厚管と同軸で、これと滑り嵌めてよい。外鞘は、挿入中に誘導針の前進に対する抵抗を小さくするよう、先細で滑らかな近端を有してもよい。

。外鞘の近端は、近位取付器具に締め嵌めするようにしてもよい。

遠位取付器具は患者から外すため、流線形で、近位取付器具まで前進し、それによって解放されたプロテーゼを通して滑らかに後退し、外鞘に入るようにすることが好ましい。

本発明による誘導針は、直線の管状自己膨張性プロテーゼとともに使用することができ、あるいはプロテーゼが二叉プロテーゼである場合に使用してもよい。

本発明による誘導針は、患者の管腔が大動脈であり、プロテーゼが大動脈流を治療するようになっている場合に使用してもよい。

別の形態では、本発明は挿入アセンブリによってプロテーゼを内部管腔内に配置する方法にあると言われ、方法は、プロテーゼを含む挿入アセンブリを内部管腔に挿入するステップと、挿入アセンブリから鞘を引き抜いてプロテーゼを露出させるステップと、プロテーゼを挿入アセンブリから解放するステップと、鞘を挿入アセンブリに戻すステップと、挿入アセンブリを後退させるステップとを含む。

プロテーゼは、近端および遠端を有し、挿入アセンブリは、プロテーゼの近端および遠端を保持するようになっている近位取付器具および遠位取付器具を含み、プロテーゼを解放するステップが、近端を解放してから遠端を解放するステップを含むことが好ましい。

鞘を挿入アセンブリに戻すステップは、遠位取付器具を近位取付器具まで前進させ、2つの器具と一緒に引き抜くステップを含んでもよい。

ステップ(b)と(c)との間で、プロテーゼは、近位取付器具と遠位取付器具とのそれぞれ縦方向および回転運動によって操作し、プロテーゼを正しく配置することができる。

プロテーゼが二叉プロテーゼである場合、鞘を引き抜くステップは、プロテーゼのサイド・アームが露出する第1位置へと鞘を引き抜くステップと、延長プロテーゼをサイド・アームに挿入するステップと、次に鞘をプロテーゼから完全に取り外すステップとを含んでもよい。

延長プロテーゼをサイド・アームに挿入するステップは、延長挿入アセ

ンブリをサイド・アームに挿入するステップを含み、延長挿入アセンブリは、カテーテルに取り付けた頂部ガイドと、カテーテル上の延長プロテゼと、延長プロテゼを保持し、頂部ガイド上に延在する鞘を含み、さらに鞘を引き抜いて延長プロテゼを露出させ、配置するステップと、鞘、頂部ガイドおよびカテーテルと一緒に引き抜くステップを含むことが好ましい。

頂部ガイドは、長い近位ノーズ延長部を含んでもよく、カテーテルは、延長プロテゼを遠位止め具と頂部ガイドとの間に取り付けた状態で、遠位止め具を含んでもよい。

別の形態では、プロテゼは二叉プロテゼであり、鞘を引き抜くステップは、プロテゼの第1サイド・アームが露出する第1位置へと鞘を引き抜くステップと、第1延長プロテゼを第1サイド・アームに挿入するステップと、次に鞘をプロテゼから完全に外して第2サイド・アームを露出させるステップと、次に第2延長プロテゼを第2サイド・アームに挿入するステップとを含む。

第1および第2延長プロテゼを第1および第2サイド・アームに挿入するステップは、以下で検討するのと同じステップを含む。

さらなる形態では、本発明は、管状グラフトおよびグラフトの長さに沿った複数の自己拡張性ステントを有する管内プロテゼで、プロテゼは近端および遠端を有し、ステントは近端および遠端が管状グラフトの内側にあり、ステントの残りの部分がグラフトの外側にあることを特徴とするプロテゼにあると言われる。

さらに、グラフトの近端に取り付けられ、前記近端より先へと延在するさらなる自己拡張性ステントも含むことができる。さらなるステントは、取付器具を含んでもよい。取付器具は、プロテゼの遠端に向かって延在する返しを備えることができる。

プロテゼは、遠端で二叉になり、短い方の脚部と長い方の脚部を設けることができる。短脚はプロテゼの外側に末端ステントを有することができ、長脚は内部遠位ステントを有する。

プロテゼ短脚に挿入する延長プロテゼもあってよく、延長プロテ

ぜは、管状延長プロテゼおよび複数の自己拡張性ステントを備え、延長プロテゼは近端および遠端を有し、ステントは近端および遠端で管状延長プロテゼの内側にあり、残りのステントはプロテゼの外側にある。

管内プロテゼは、短脚と長脚との両方が各脚部の外部末端ステントおよび延長プロテゼを有し、各延長プロテゼが管状延長プロテゼおよび複数の自己拡張性ステントを備え、延長プロテゼが近端および遠端を有し、ステントは近端および遠端が管状延長プロテゼの内側にあり、残りのステントがプロテゼの外側にあるよう構築することができる。

本発明による管内プロテゼの各ステントは、ジグザグ形ステントでよい。

概して、プロテゼを圧縮して細い挿入器具に入れ、次にプロテゼがほぼ必要な位置に至るまで挿入器具を大腿動脈などの血管を通して前進させ、次にプロテゼの近端で取付手段を解放する前に注意深く位置決めし、次にプロテゼの遠端を解放する前に必要に応じて再配置することによって、プロテゼを正確に配置し、解放することができる装置が提供されることが、本発明により分かる。

図面の簡単な説明

好ましい実施態様の構成および器具を操作できる方法は、本発明の好ましい実施態様および種々の実施態様の器具を使用する方法を示す添付図面の助けにより、さらに明白になる。理解しやすいように、プロテゼを挿入する管腔または脈管は、図18以外の図では図示しない。

図1は、プロテゼを部分的に配置した、本発明による誘導針の第1の実施態様を斜視図で示す。

図2は、十分に装填し、患者に導入する用意が調った、図1に示すような誘導針の第1の実施態様を示す。

図3は、プロテゼの次の配置段階にある図2の実施態様を示す。

図4は、配置の近端を解放する段階で図2の実施態様を示す。

図5は、配置の遠端を解放する段階を示す。

図6は、遠位取付器具の近位取付器具への前進を示す。

図7は、誘導針の引き抜きを示す。

図8は、プロテーゼの遠端の周辺にある誘導針の部分を詳細に示す。

図8Aは、プロテーゼの遠端の周辺にある誘導針の部分の別の実施態様を詳細に示す。

図8Bは、遠位取付器具を近位取付器具へと前進させた図8Aの実施態様を示す。

図9は、プロテーゼの近端の周辺にある誘導針の部分を詳細に示す。

図10は、止血シールの周辺にある誘導針の部分を詳細に示す。

図11は、トリガー線解放機構の周辺にある誘導針の部分を詳細に示す。

図12は、ピン・バイス・クランプの周辺にある誘導針の部分および医薬品誘導管を詳細に示す。

図13A～図13Cは、二又プロテーゼに誘導するようになっている、本発明による誘導針の別の実施態様の部分を示す。

図14は、延長プロテーゼを誘導するようになっている、本発明による誘導針の別の実施態様を示す。

図15は、本発明による延長プロテーゼを有する二又プロテーゼの実施態様を示す。

図16は、本発明による2本の延長プロテーゼを有する二又プロテーゼの実施態様を示す。

図17は、大動脈回腸動脈に配置するよう意図された本発明によるプロテーゼの実施態様を示す。

図18は、動脈瘤のある大動脈内に配置した本発明によるプロテーゼを示す。

詳細な説明

次に、図類特に図1から図12に示す実施態様をさらに詳細に見てみると、本発明による誘導針などの血管内膜装置は概ね、外部操作区間1、遠位取付領域2および近位取付領域3を備えることが分かる。

図9に詳細に示す遠位取付領域3は、近端から延在する長い先細の可撓

性延長部11を有する円筒形スリーブ10を含む。延長部11は、内部縦開口12を有し、これによって挿入線13に沿って前進することができ、例えば医療処置の配置および展開段階で造影剤を使用して血管造影法を実行できるよう、医薬品を供給することができる。肉薄金属管15が延長部11に締め付けられ、誘導針全体を通して操作区間へと延在して、注射器の接続手段16で終了し、したがって医薬品を金属管に、そして延長部11に導入し、開口14を通して出すことができる。肉薄金属管15は可撓性であり、したがって誘導針は大腿動脈などの蛇行性脈管に沿って前進することができ、近位取付領域3を縦方向および回転方向に操作することができる。

プロテゼ20は、誘導針から解放された後に膨張できる弾性ステント19を有する自己膨張タイプである。誘導針内に保持されたプロテゼは、遠端から延在した自己拡張性ジグザグ形ステント21を含み、ジグザグ形ステント21は圧縮された状態で近位取付領域3の円筒形スリーブ10内に保持され、これは、近位取付器具10の側部にある開口23を通して延在し、ジグザグ形ステントのループの1つで受けるトリガー線22によって保持される。トリガー線22は誘導針の長さの大部分に沿って延在し、近位線解放機構24の操作領域で出る。

プロテゼ20は、図2で特に分かるように、挿入のために器具を組み立てた時、近位取付器具10の円筒形スリーブ10上で受けるよう前進する外部スリーブ30によって、圧縮状態に保持される。外鞘30は患者の体外の外部操作区間、およびその把持および止血密封手段へと遠位方向に延在する。

図8で特に分かるように、プロテゼ20の遠端は、遠位取付器具40内に保持され、これは患者の体外および操作領域1へと遠位方向に延在する肉厚プラスチック管41に取り付けられる。肉厚管は肉薄管15と同軸上にあって、その半径方向外側にあり、鞘30は肉厚管41と同軸上にあって、その半径方向外側にある。プロテゼ20の遠端42はループ43を有し、遠位トリガー線44がこれを通して延在する。遠位トリガー線は、遠位取付器具の開口45を通して、肉薄管15と肉厚管41との間の環状領域に入る。これは、近位トリガー線と同様で、これも図2で示すように、肉厚管41と肉薄管15との間の環状空間

を通過して操作器具へと延在し、遠位線解放機構25で出る。

図8Aおよび図8Bで示すような別の実施態様では、肉厚管160は先細端161を有し、これを通過して肉薄管162が延在する。肉厚管160と肉薄管162との間に低摩擦ライニング163を設け、したがって前者は後者上を容易に摺動する。近位解放線165および遠位解放線167は肉厚管160の中にある。それぞれ先細部分161の遠位方向の開口166および168から出る。遠位解放線167は、プロテゼ171の遠端にあるループ170を通過し、開口172を通過して先細部分161に再度入る。

図8Bに示すように、遠位取付領域が近位取付領域へと前進すると、先細部分161が管175に填り、2つを一緒に後退させる平滑な表面を提供する。

図10で特に分かるように、使用時に患者の体外に残る止血シールは、止血シール27への外部スリーブ30を締め付ける締付けカラー26を有する。止血シール26は、肉厚管41を封止して止血シールを提供するシリコン製シール・リング28と、肉厚管41と外部スリーブ30との間に医薬品を導入する側管29とを有する。

図11で特に分かるように、外部操作区間の解放線起動区間は本体36を有し、その端部に肉厚管41が装着され、肉薄管15がそれを通る。近位線解放機構24と遠位線解放機構25は両方とも、本体36上に摺動できる状態で装着される。それは、近位線解放機構24が移動しないと遠位線解放機構25が移動できないよう配置される。つまり、プロテゼの近端を解放するまで、プロテゼの遠端を解放することができない。近位線解放機構24と遠位線解放機構25とのそれぞれに締付ねじ37を設け、プロテゼのいずれかの端が不注意で早期に解放されるのを防止する。止血シール38は、個々の解放線が本体36を出て個々の解放機構へと延在できるよう設けられる。

図12で特に分かるように、肉厚管41から本体36の他方端へと装着されたピン・バイス39がある。ピン・バイス39は、ねじ込まれるとバイスの顎47を肉薄金属管15に締め付けるねじキャップ46を有し、したがって肉薄管15は本体26とともにしか移動できず、肉薄管が肉厚管とともにしか移動で

きなくなる。

次に図2から図7を見てみると、これは本発明のこの実施態様によるプロテーゼの種々の配置段階を示す。

案内線（図示せず）を大腿動脈に導入し、その先端がプロテーゼを配置すべき領域より上になるまで前進させる。

図2には、完全に組み立てて患者に導入する用意が調った誘導針アセンブリが図示されている。プロテーゼ20は、各端がそれぞれ近位および遠位保持アセンブリで保持され、外部スリーブ30で圧縮される。移植先が大動脈瘤である場合は、誘導針アセンブリを図2に示したような形態の案内線に被せ、大腿動脈を通して挿入し、X線造影技術（本明細書では検討せず）で配置することができる。

図3では、誘導針アセンブリが選択した位置に到達したら、外鞘30をちょうど遠位取付器具40の近位側まで引き抜き、したがってプロテーゼ20が半径方向に膨張できるよう解放されるが、最も近位側のジグザグ形ステント21はまだ近位取付器具10内に保持され、その遠端42は外鞘30内に保持される。

ピン・バイス39を解放して、肉薄管15が肉厚管41に対して少々移動できるようにすることにより、プロテーゼ20を身体管腔内の所望の位置に正確に配置するよう、延長、短縮、回転または圧縮することができる。プロテーゼの配置を補助するため、プロテーゼに沿って既知の位置にX線不透性マーカー（図示せず）を配置してもよい。

図4では、近位線解放機構24（図3）の遠位方向の動作により、近位トリガー線22（図3）が引き抜かれている。この段階で、近位線解放機構24をピン・バイス39、46および注射器の接続手段16を通過させることにより、近位線解放機構24および近位トリガー線22は、完全に外されている。次に、ピン・バイス39のねじキャップ46を緩め、肉薄管15を近位方向に押しして近位取付手段10を近位方向に移動させ、それによってプロテーゼの近端でジグザグ形ステント21を近位取付手段10から解放できるようにする。この段階で、ジグザグ形ステント21上のフックまたは返し26が管腔の壁に食い込み、プ

ロテータを保持する。この段階から、プロテータの近端は再度移動できなくなる。

プロテータ42の遠端はまだ、ループ43を中に保持した状態で遠位取付手段40に保持されている。外鞘30は、遠位取付器具40の遠位側に引き抜いて、取付器具の遠端を露出できるようになっている。

しかしこの段階で、プロテータの遠端はまだ移動することができ、したがってプロテータを回転、延長、短縮または他の方法で移動させ、プロテータを正確に配置することができる。配置すべきプロテータが二又グラフトである場合、この段階での動きは短脚が回腸動脈と反対方向に配向されることを保証できる。

図5では、遠位トリガー線44を外して、プロテータの遠端42が解放されている。この段階で、遠位線解放機構25をピン・バイスおよび注射器の接続手段16を通過させることにより、遠位線解放機構25および遠位トリガー線44は、完全に外されている。このように末端遠位ジグザグ形ステントのループ43が供給され、プロテータは自由に脈管の壁へと膨張し、誘導針をいつでも外すことができる。

取り外しの第1段階を図6に示し、ここでは遠位取付器具40が前進して近位取付器具10の後部で受けられ、次に先細可撓性延長部11を含む近位取付器具10および遠位取付器具40が図7に示すように一緒に外される。この図では、外部スリーブ30が前進して近位取付器具10と遠位取付器具40との接合部を覆い、近位取付器具10、先細可撓性延長部11および遠位取付器具40とともに外されるが、これは別個に外してから、後に外部スリーブ30を外すこともできる。これは、さらなる外科処置が必要な場合、何らかの利点があることもある。他の外科器具を前進させる開けた路が提供されるからである。

図13Aから図13Cは、自己膨張性二又プロテータを有する、本発明による誘導針の使用を示す。

図13Aから図13Cでは、誘導針の近位取付器具および遠位取付器具を含む誘導針の断面を、二又プロテータとともに示す。

二又プロテータ50は、近位取付器具52と遠位取付器具53との間で

外鞘51内に、図1から図12に示したのと同じ近位取付器具52および遠位取付器具53への個々の取付具で保持される。近位方向に延在するジグザグ形ステント57が、近位取付器具52内に保持される。

図13Bで示すように、近位トリガー線61を解放し、近位取付器具52を前進させた後、プロテーゼ50の56の近端が解放され、ジグザグ形ステント57が自由に膨張する。この段階で、プロテーゼ50の遠端58はまだ遠位取付手段53内に保持されている。

この段階で、延長部片59は、図13Cに示すように他の大腿動脈からの別個の誘導針によって、サイド・アーム60に挿入することができる。遠位取付器具の解放および誘導針の引き抜きは、図1から図12に関して検討したのと同じ方法で進めることができる。

延長プロテーゼの誘導に適した本発明による誘導針の実施態様が図14に図示され、これは、その長さに沿って誘導針の種々の部分を示す。

実施態様は、近端から開始して、肉薄金属管71に装着された先細可撓性延長部70を含む。先細可撓性延長部70は縦方向の開口73を含む。肉薄金属管71は、先細可撓性延長部に締め付けられ、使用時に先細可撓性延長部から患者の体外へと遠位方向に延在する。肉薄金属管71は、必要に応じて医薬品を誘導するため、コネクタ74へと延在する。延長プロテーゼ誘導針には、近位または遠位取付器具がない。プロテーゼ75は可撓性延長部の遠端80と肉厚可撓性管77の近端78との間に保持される。鞘79が肉厚管77に滑り嵌められ、挿入プロセスの間、可撓性延長部70の遠端80まで延長プロテーゼに装着され、誘導針が脈管構造を前進するための平滑な表面を提供する。

延長プロテーゼを誘導する方法は、以下の通りである。

案内線（図示せず）を大腿動脈に誘導し、先端がプロテーゼを配置すべき領域より上になるまで前進させる。次に、延長プロテーゼがプロテーゼの短脚内にある1つのステント全体と重なるまで、振動回転動作で誘導針を案内線上で前進させる。次に、鞘79を引き抜く前に、肉厚管77を所定の位置に保持しながら、最終位置の点検を実行することができる。次に、可撓性延長部70を肉厚管77まで引き抜き、その間のギャップを鞘79で覆うことによって、誘導針を

外することができる。

図15は、本発明による延長プロテーゼを有する二又プロテーゼの実施態様を示す。二又プロテーゼ90は、本体部分91、短脚92および長脚93を有する概ね逆Y字形の形状を有する。プロテーゼの本体は、ダクロンなどの管状の編組合成材料から構成する。プロテーゼ90の近端には、プロテーゼの端より先まで延在して、遠位方向に延在する返し96を有する第1ジグザグ形ステント95がある。プロテーゼは、これに装着され、その長さに沿って延在する幾つかのジグザグ形ステントを有する。近端94に最も近いステント97は、管状材料の内側にあり、したがって外側は、使用時に配置されるべき脈管の内壁と噛み合って血流に対するバリアを提供する平滑な表面を呈する。長脚の遠端99に最も近いステント98も管状材料の内側にあり、したがって外側は、使用時に配置されるべき脈管の内壁と噛み合って血流に対するバリアを提供する平滑な表面を呈する。これらの内部ステントの間で、残りのステント100は管状材料の外側に配置され、したがってプロテーゼを通る血流に対する制限を最小にし、プロテーゼ内に血栓症が生長する部位を最小にする。各ステントは、特に101で示すように、管状材料に縫い付けられる。

長脚93は、管状材料の端より先まで延在し、遠位取付手段として作用する末端内部ステント98の1つのループ43を有する。

使用時には、本発明のこの実施態様によるプロテーゼは、大動脈内に適合するようになっていて、したがって端94は腎動脈のすぐ遠位側にあり、第1ジグザグ形ステント95は腎動脈まで、またはそれより先に延在する。これは細い線から構成されているので、その上に延在しても腎動脈を遮断しない。長脚93は、回腸動脈の一方を下方向に延在し、短客は他の回腸動脈よりわずか手前の大動脈で終了する。

短脚の遠端92に最も近い末端ステント102は、管状材料の外側にあり、したがって内側は、使用時に延長プロテーゼの一方端の外側と噛み合う平滑な表面を呈する。

延長プロテーゼ104は、上記で検討したような方法により、短脚に填るようになっている。延長プロテーゼ104は、ダクロンなどの管状剛性材料か

ら構成され、末端内部ステント105および複数の外部中間ステント106を有する。

図16は、本発明による2本の延長プロテーゼを有する二又プロテーゼの実施態様を示す。二又プロテーゼ110は、本体部分111、短脚112および長脚113を有する概ね逆Y字形の形状を有する。プロテーゼの本体は、ダクロンなどの管状編組合成材料から構成する。プロテーゼ110の近端114には、プロテーゼの端より先まで延在して、遠位方向に延在する返し116を有する第1ジグザグ形ステント115がある。プロテーゼは、これに装着され、その長さに沿って延在する幾つかのジグザグ形ステントを有する。近端114に最も近いステント117は、管状材料の内側にあり、したがって外側は、使用時に配置されるべき脈管の内壁と噛み合って血流に対するバリアを提供する平滑な表面を呈する。長脚および短脚両方の遠端99に最も近い末端ステント118は、管状材料の外側にあり、したがって使用時に延長プロテーゼの一方端の外側と噛み合う平滑な表面を呈する。

これらの末端ステントの間で、残りのステント119は管状材料の外側に配置され、したがってプロテーゼを通る血流に対する制限を最小にし、プロテーゼ内に血栓症が生長する部位を最小にする。各ステントは、特に101で示すように、管状材料に縫い付けられる。

長脚113は、管状材料の端より先まで延在し、遠位取付手段として作用する末端内部ステント118の1つのループ43を有する。

延長プロテーゼ120および121は、上記で検討したような方法により、短脚および長脚両方に填るようになっている。延長プロテーゼ120および121はそれぞれ、ダクロンなどの管状合成材料から構成され、末端内部ステント122および複数の外部中間ステント123を有する。

使用時には、本発明のこの実施態様によるプロテーゼは、大動脈内に適合するようになっていて、したがって端114は腎動脈のすぐ遠位側にあり、第1ジグザグ形ステント115は腎動脈まで、またはそれより先に延在する。これは細い線から構成されているので、その上に延在しても腎動脈を遮断しない。長脚113は、回腸動脈の一方を下方向に延在し、短客は他の回腸動脈よりわずかに

手前の大動脈で終了する。延長プロテーゼは、配置時、各回腸動脈を下方向に延在する。

図17は、大動脈回腸動脈に配置することを意図した本発明によるプロテーゼの実施態様を示す。プロテーゼ130は、本体部分より直径が小さい1本脚132を下方向に延在する本体部分131を有する、概ね先細の管状形状を有する。プロテーゼの本体は、ダクロンなどの管状編組合成材料から構成される。プロテーゼ130の近端134には、プロテーゼの端より先まで延在して、遠位方向に延在する返し136を有する第1ジグザグ形ステント135がある。プロテーゼは、これに装着され、その長さに沿って延在する幾つかのジグザグ形ステントを有する。近端134に最も近いステント137は、管状材料の内側にあり、したがって外側は、使用時に配置されるべき脈管の内壁と噛み合って血流に対するバリアを提供する平滑な表面を呈する。脚の遠端132に最も近いステント138も、管状材料の内側にあり、したがって外側は、使用時に延長プロテーゼの一方端の外側と噛み合う平滑な表面を呈する。これらの末端ステントの間で、残りのステント140は管状材料の外側に配置され、したがってプロテーゼを通る血流に対する制限を最小にし、プロテーゼ内に血栓症が生長する部位を最小にする。各ステントは、特に101で示すように、管状材料に縫い付けられる。

脚132は、管状材料の端より先まで延在し、遠位取付手段として作用する末端内部ステント138の1つのループ43を有する。

使用時には、本発明のこの実施態様によるプロテーゼは、大動脈内に適合するようになっていて、したがって端134は腎動脈のすぐ遠位側にあり、第1ジグザグ形ステント135は腎動脈まで、またはそれより先に延在する。これは細い線から構成されているので、その上に延在しても腎動脈を遮断しない。長脚132は、回腸動脈の一方を下方向に延在する。他方の回腸動脈は大腿動脈を介して挿入されたプラグで閉じられ、クロス・グラフトが回腸動脈間に外科的に挿入されて、両方の回腸動脈に血流を提供する。

図18は、動脈瘤がある動脈内にある、本発明の実施態様による配置済みプロテーゼを示す。

動脈瘤150は、腎動脈153と回腸動脈154間の動脈の風船様拡大

部である。図15に示すようなプロテーゼを動脈内に配置し、したがってこれが動脈瘤を広げ、動脈から2本の回腸動脈への血流を可能にする。内部にステントを有するプロテーゼ90の近位部分94が、動脈瘤より上で動脈152の壁にもたれ掛かり、したがって良好な密封が獲得されることが分かる。部分94より先まで延在するジグザグ形ステント95は、腎動脈の入口の上に延在するが、ステントの線が細いので閉塞は生じない。プロテーゼ99の遠端は回腸動脈の一方の壁を封止し、延長プロテーゼの遠端155は他方の回腸動脈の壁にもたれ掛かる。

プロテーゼ90と延長プロテーゼ104との接合部156は密封される。短脚112の平滑な内面と延長プロテーゼ104の近端の平滑な外面との間が、滑らかに接続されるからである。

本発明によるプロテーゼのサイズは、実際に脈管の健全な部分と縋り嵌めして、脈管の内壁を良好に封止するよう選択することができる。プロテーゼは、最も広い部分が、動脈に填る場合は20mmから32mmの範囲、回腸動脈に填る場合は8mmから24mmの範囲でよい。

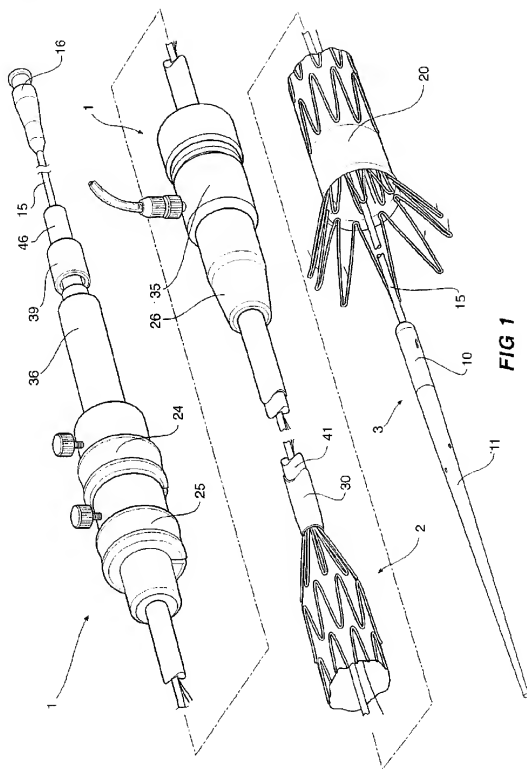
図15に示す実施態様は、覆われていない近位ステントの長さを除いて、120mmから180mmの全長を有することができ、延長プロテーゼは35mmから125mmの長さ、および8mmから24mmの直径を有することができる。プロテーゼの短脚と延長プロテーゼの近端との重なり量は、15mmから21mmである。

図16に示す実施態様は、覆われていない近位ステントの長さを除いて、100mmから130mmの全長を有することができ、二又プロテーゼの短脚と長脚との長さの差は30mmでよい。短い方の延長プロテーゼは、65mmから125mmの長さ、および8mmから24mmの直径を有することができる。プロテーゼの短脚と延長プロテーゼの近端との重なり量は、15mmから22mmである。長い方の延長プロテーゼは、35mmから125mmの長さ、および8mmから24mmの直径を有することができる。プロテーゼの長脚と短い方の延長プロテーゼの近端との重なり量は、15mmから22mmである。

図17に示す実施態様は、覆われていない近位ステントの長さを除いて

、90 mmから180 mmの全長を有することができる。プロテゼは、最も広い部分が、動脈に填る場合は20 mmから32 mmの範囲、回腸動脈に填る場合は8 mmから24 mmの範囲でよい。

【図1】



【図2】

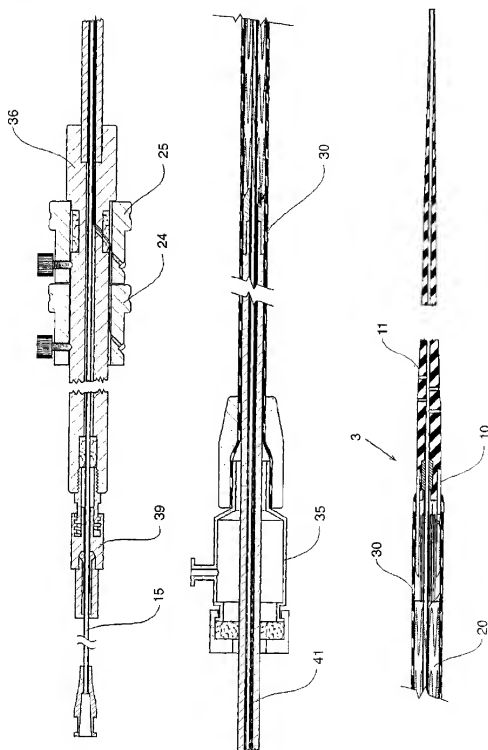


FIG 2

【図3】

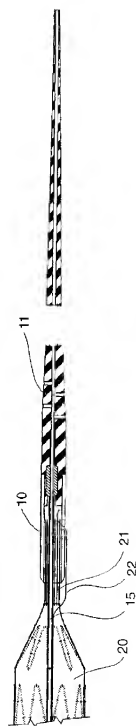
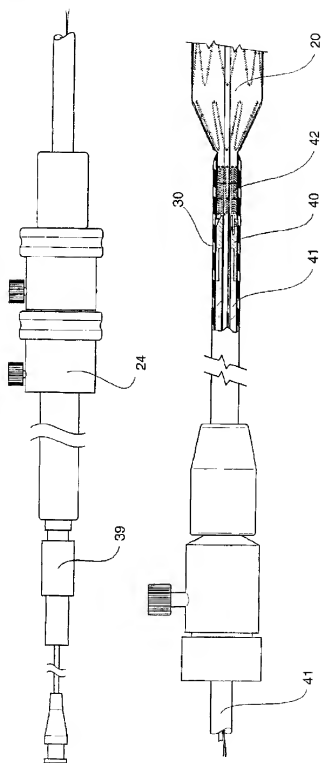


FIG 3

【図4】

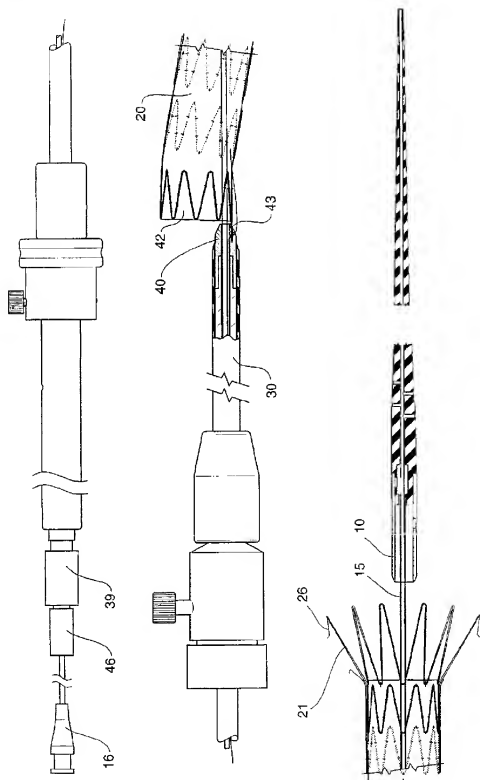
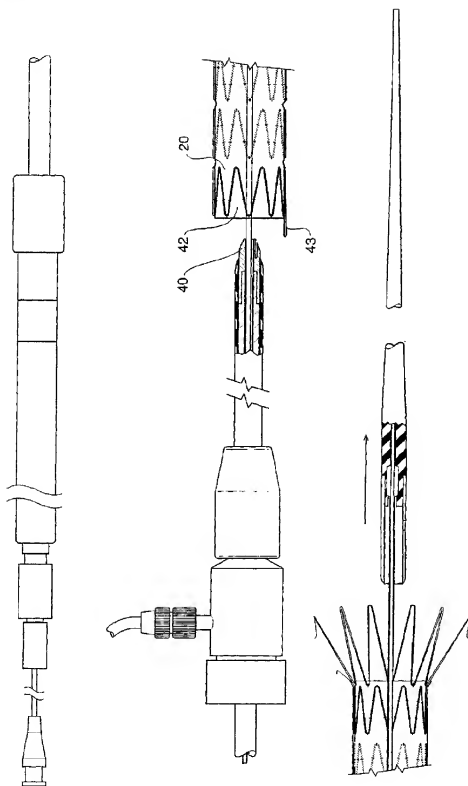
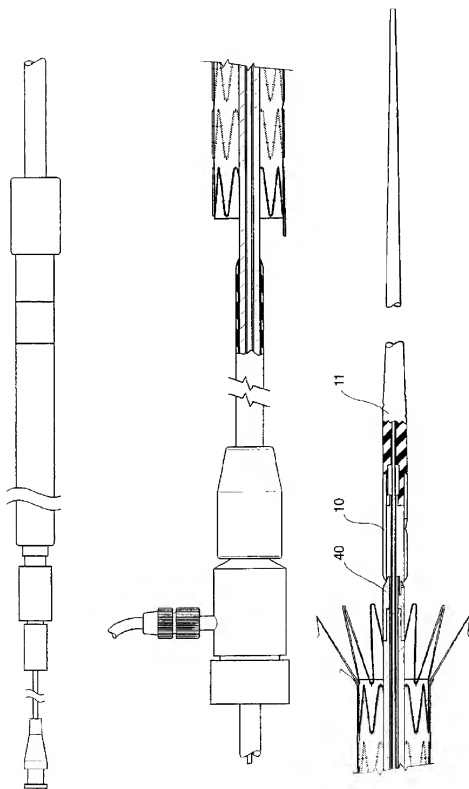


FIG 4

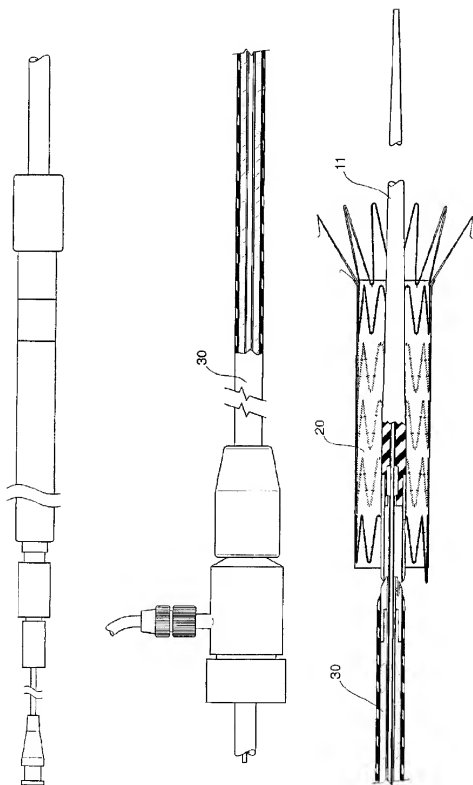
【図5】



【図6】



【図7】



【図8】

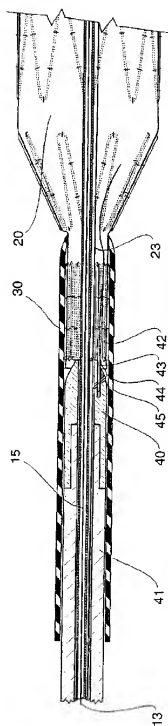
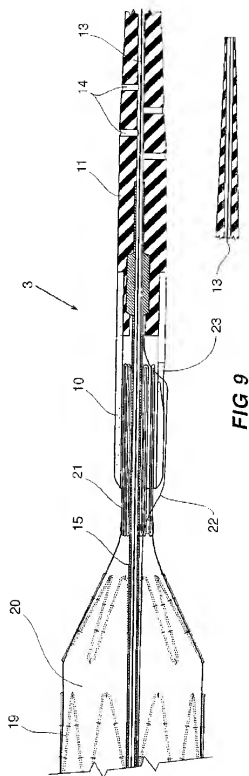
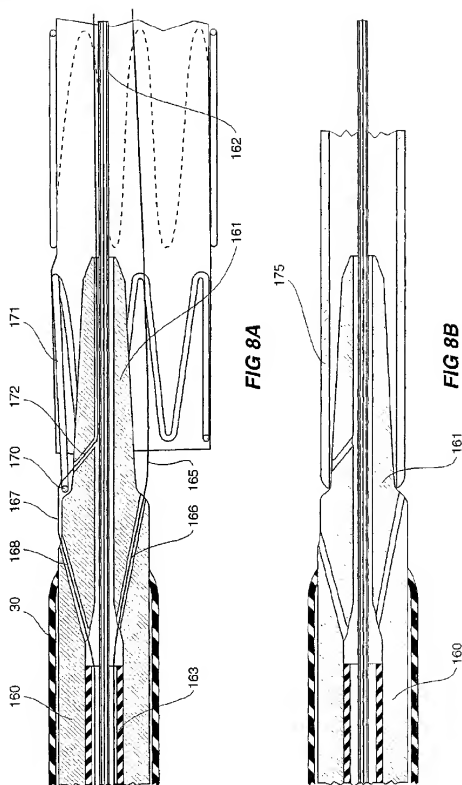


FIG 8

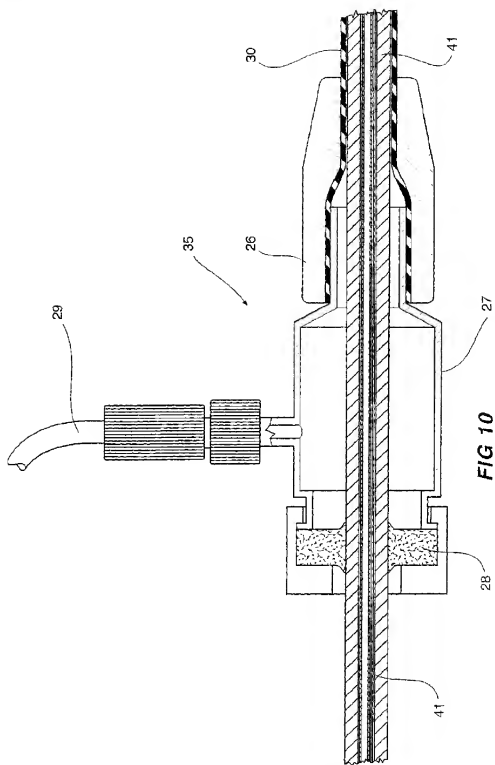
【図9】



【図8】



【図10】



【図 11】

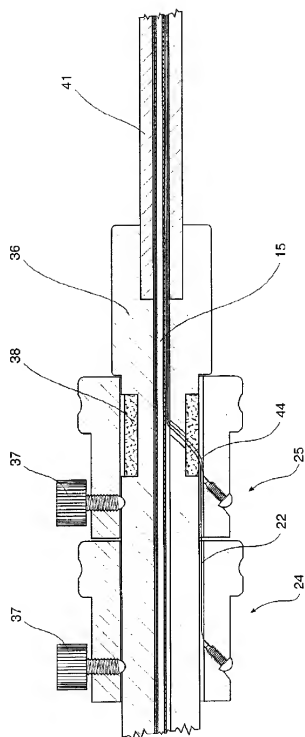
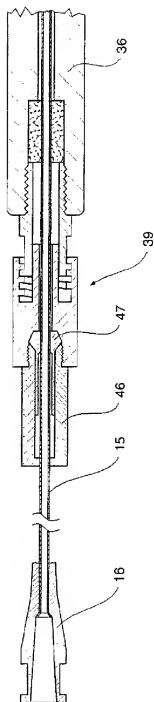


FIG 11

【図12】



【図13】

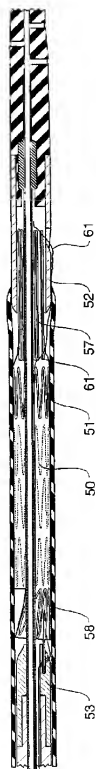


FIG 13A

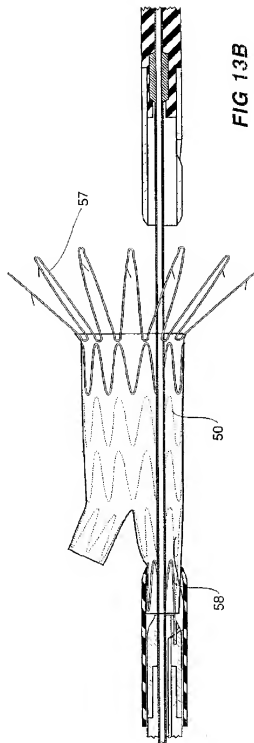


FIG 13B

【図13】

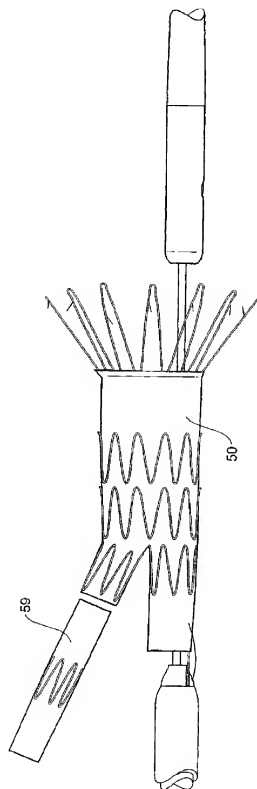
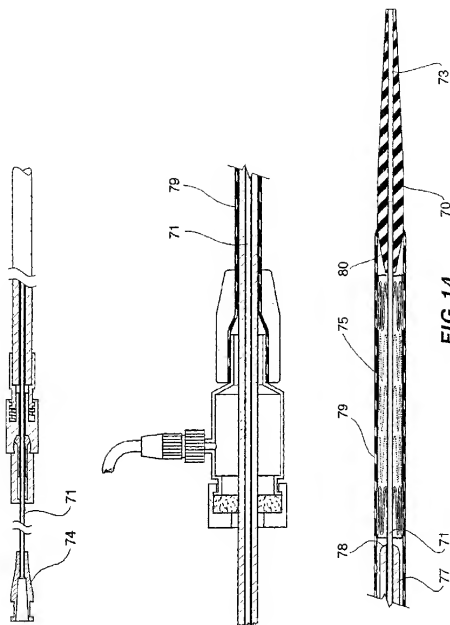


FIG 13C

【図14】



【图15】

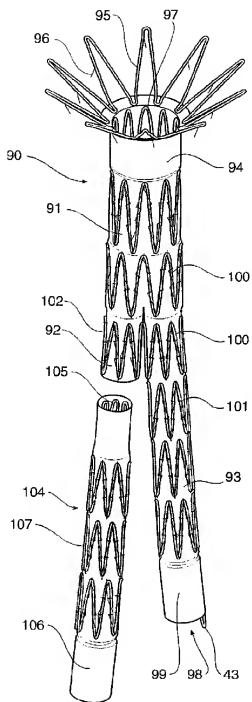


FIG 15

【図16】

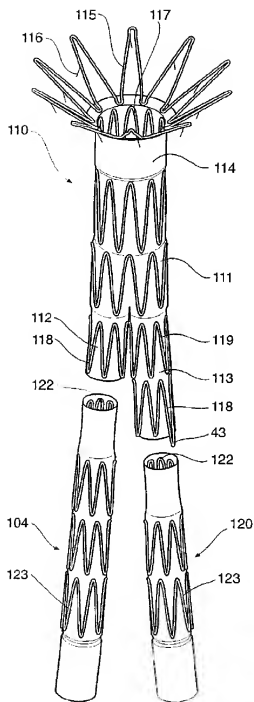


FIG 16

【図17】

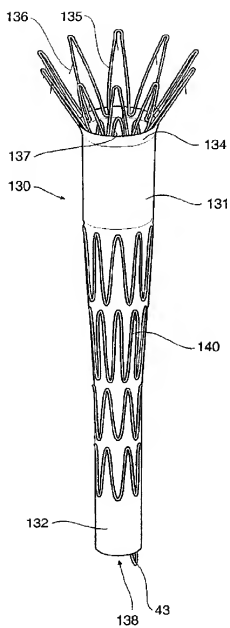


FIG 17

【図18】

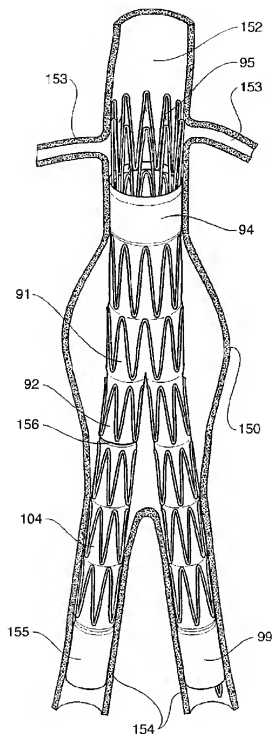


FIG 18

【国際調査報告】

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/JP 98/00383

A. CLASSIFICATION OF SUBJECT MATTER		
Int. Cl. ⁷ : A61F 2/06; A61M 29/00		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols)		
IPC: A61F; A61M		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
AU IPC: A61F 2/06		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
WPAT: introduce replace, deploy, sheath, sleeve cover		
IAPIO: endovascular vein arter, prosthe graft		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 461791 A1 (BARONE et al) 18 December 1991 entire document	43,47-54
X	EP 637454 A1 (ENDOASCULAR TECHNOLOGIES INC) 8 February 1995 column 19 line 23 to column 22 line 39 figures 27 to 83	1-4,8,43
X	EP 684022 A2 (ENDOASCULAR TECHNOLOGIES INC) 29 November 1995 column 29 line 8 to column 34 line 31, figures 29 to 36	1-4,8,43,47-54
P,X	EP 795305 A2 (ENDOASCULAR TECHNOLOGIES INC) 17 September 1997 entire document	43,47-54
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex		
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Date of the actual completion of the international search 21 July 1998		Date of mailing of the international search report 24 JUL 1998
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WOOLLEN ACT 2606 AUSTRALIA Facsimile No.: (02) 6283 3929		Authorized officer MATTHEW FORWARD Telephone No.: (02) 6283 2606

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/AU 98/00383

C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication where appropriate, of the relevant passages	Relevant to claim No
X	US 5415664 A (PINCHUK) 16 May 1995 column 3 lines 21 to 63, column 7 line 64 to column 9 line 45, figures 9 to 116	1-4,43
P,X	US 5634941 A (WINSTON et al) 3 June 1997 column 4 line 20 to column 6 line 17, figures 5 to 7	43, 47-54
X	WO 96/24308 A (COOK INCORPORATED) 15 August 1996 entire document	1-4, 8, 43, 47-54
P,A	WO 98/07388 A (SCIMED LIFE SYSTEMS, INC) 26 February 1998	
Y	WO 96/38101 A (MEADOX MEDICALS, INC) 5 December 1995 page 6 line 8 to page 8 line 9, figures	55-58, 63
Y		59-62
Y	US 5122154 A (RHODES) 16 June 1992 figure 1	55-58, 63
Y	FR 2722678 A (B BRAUN CELSA SA) 26 January 1996 figures	59-62
A	WO 96/33672 A (IMPRA, INC) 31 October 1996 page 13 line 4 to page 14 line 8, figure 1	55
A	EP 712614 A (ADVANCED CARDIOVASCULAR SYSTEMS INC) 22 May 1996 figures 9 to 11, column 11 line 17 to column 13 line 39	55

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/AU 98/00383

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

- 1 ☐ Claims Nos. _____
because they relate to subject matter not required to be searched by this Authority, namely: _____

- 2 ☐ Claims Nos. _____
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically _____

- 3 ☐ Claims Nos. _____
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Claims 1 to 42 relate to introducing a vascular prosthesis such that the position of the distal and proximal ends of the prosthesis may be manipulated. Claims 43 to 54 define a method wherein a sheath is positioned over a prosthesis prior to insertion at a bifurcated site, removed to place the prosthesis and replaced to remove the introducer. Claims 55 to 63 relate to a prosthesis with stents on the inside at the proximal and distal ends.

- 1 ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
- 2 ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
- 3 ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos. _____.

- 4 ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos. _____.

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No.
PCT/AU 98/00383

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Patent Document Cited in Search Report			Patent Family Member			
EP	461791	AU	78092/91	AU	77546/94	BR 9102548
		CA	2043562	JP	4231954	US 5360443
		ZA	9104248	US	5578072	US 5571173
		US	5578071	US	5591229	US 5643208
		US	5693087	US	5522880	US 5571171
		US	5683452	AU	74328/94	AU 16615/97
		AU	16617/97	AU	16618/97	BR 9403662
		CA	2132815	EP	646365	JP 8047503
		ZA	9407492			
EP	637454	AU	64747/94	AU	74253/96	CA 2125258
		JP	7059802	US	5749920	US 5693083
		US	4787869	US	5104399	US 5275622
		US	5397345	US	5562728	US 5662700
		US	5669936	AU	34392/89	AU 38261/93
		AU	40886/96	CA	1335528	EP 407425
		EP	688544	JP	3503246	WO 89/08433
		AU	80417/91	AU	70204/94	AU 12219/97
		CA	2046974	EP	466518	EP 680734
		IL	98820	JP	5076554	AU 46847/96
		CA	2207596	EP	797415	WO 96/18361
EP	684022	AU	71438/94	AU	62193/96	CA 2150138
		JP	8038486	US	5628783	US 5769885

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No.
PCT/AU 98/00383

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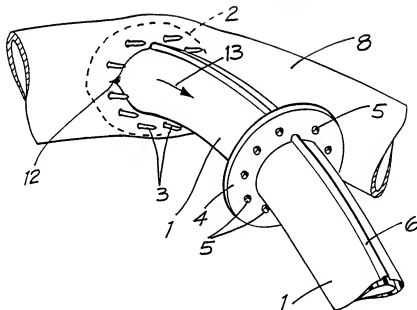
Patent Document Cited in Search Report			Patent Family Member		
	CA	2065634	EP	508473	EP 795305
	EP	832617	JP	6023031	US 5489295
	US	5609625			
EP	795305	CA	2065634	EP	508473
		JP	6023031	US	5489295
		US	5628783	US	5769885
		AU	62193/96	CA	2130138
		JP	8038486	EP	684022
US	5415664	CA	2185886	EP	752896
		US	5415664	WO	95/26775
US	5634941	EP	655898	US	5366473
WO	96/24308	AU	49722/96	CA	2212286
		US	5693084	US	5720776
		CA	2081424	EP	539237
		US	5387235	US	5562726
		JP	5305092	AU	54780/96
		EP	747020	JP	9098974
WO	98/07388	AU	40622/97		
WO	96/38101	AU	59598/96	EP	831753
US	5122154	NONE			
FR	2722678				
CONTINUED					

フロントページの続き

(81)指定国 EP(AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OA(BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), AP(GH, GM, KE, LS, MW, SD, SZ, UG, ZW), EA(AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁵ : A61F 2/06	A1	(11) International Publication Number: WO 93/00868 (43) International Publication Date: 21 January 1993 (21.01.93)
(21) International Application Number: PCT/AU92/00328 (22) International Filing Date: 3 July 1992 (03.07.92) (30) Priority data: PK 7057 4 July 1991 (04.07.91) AU (71)(72) Applicant and Inventor: OWEN, Earl, Ronald [AU/AU]; Microsurgery Centre, 1 Esther Street, Surry Hills, NSW 2010 (AU). (74) Agent: GRIFFITH HACK & CO.; G.P.O. Box 4164, Sydney, NSW 2001 (AU). (81) Designated States: AT, AU, BB, BG, BR, CA, CH, CS, DE, DK, ES, FI, GB, HU, JP, KP, KR, LK, LU, MG, MN, MW, NL, NO, PL, RO, RU, SD, SE, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LU, MC, NL, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, SN, TD, TG).		Published <i>With international search report.</i>

(54) Title: TUBULAR SURGICAL IMPLANT**(57) Abstract**

A tubular surgical implant particularly suitable for use in heart bypass surgery comprising a tube (1) having a flange (2) adapted to be folded and inserted into a cut in a vessel (8). The flange has a series of spikes (3) parallel to the tube which pass through the vessel wall and are engaged with holes (5) in a locking ring (4) slidable on the tube (1). The implant is typically connected between an aorta and a distal coronary artery in a heart bypass operation.

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"TUBULAR SURGICAL IMPLANT"

TECHNICAL FIELD

This invention relates to a tubular surgical implant and has been devised particularly though not solely for use as a by-pass device and specifically as a coronary by-pass device.

BACKGROUND ART

So-called "heart by-pass" surgery is relatively common and is necessitated by blockage or partial blockage by narrowing of the coronary arteries causing ischaemia or a lack of blood supply to the heart muscle, distally. The pain felt as a result is known as angina and the result can be heart attack, death or recovery with damage to the heart muscle. The present treatment by way of heart by-pass surgery is effective but is expensive to carry out, time consuming, and requires stopping the heart and placing the patient on a life-support artificial heart-lung machine using large quantities of blood. Surgeons must then harvest leg veins or chest arteries or both to sew into position as a by-pass from the aorta to the distal coronary artery.

It is desirable to provide a much less complicated procedure for carrying out a by-pass operation, which is not only faster and less expensive to perform, but also results in less risk to the patient.

DISCLOSURE OF THE INVENTION

The present invention therefore provides a tubular surgical implant adapted to be joined to a wall of a vessel or hollow organ such that the implant opens into the interior of the vessel or organ, said implant comprising an open ended tube, a deformable flange at one end of the tube, a plurality of spikes extending from the flange, alongside and generally parallel to the tube, and a locking ring arranged to slide axially on the tube, the locking ring incorporating a plurality of holes aligned with and adapted to receive the spikes.

Preferably the locking ring is keyed to the tube, preventing rotation of the ring relative to the tube.

Preferably the spikes and the holes in the locking ring are provided with a locking mechanism arranged to retain the spikes within the holes when the locking ring is engaged with the spikes.

5 The flange may be deformable relative to the tube such that the flange may be deformed to lie against the tube for insertion into an opening in the wall of the vessel or organ.

10 Alternatively the flange may be deformable across one or more hinge lines in the flange, allowing parts of the flange to bend back against the tube for insertion into an opening in the wall of the vessel or organ.

15 In one form of the invention the implant is adapted to connect two vessels or hollow organs and is provided with a flange and locking ring at both ends of the tube.

Preferably the tube and the flange are made of a plastics mesh which allows for incorporation of human tissue.

20 In a further aspect the invention provides a method of connecting two vessels or hollow organs by way of a surgical implant, comprising the steps of; providing a tubular surgical implant adapted to be joined to a wall of a vessel or organ such that the implant opens into the interior of the vessel or organ, said implant comprising
25 an open ended tube, a deformable flange at one end of the tube, a plurality of spikes extending from the flange, alongside and generally parallel to the tube, and a locking ring arranged to slide axially on the tube, the locking ring incorporating a plurality of holes aligned
30 with and adapted to receive the spikes; cutting a hole or slit in the tissue wall of the first vessel or organ, inserting the end of the tube into the hole or slit with the flange deformed, allowing or causing the flange to open behind the tissue wall, engaging the spikes through
35 the tissue wall and sliding the locking ring on the tube until the spikes are engaged with the holes in the locking ring.

BRIEF DESCRIPTION OF DRAWINGS

Notwithstanding any other forms that may fall within its scope, one preferred form of the invention will now be described by way of example only with reference to the accompanying drawings, in which:-

Fig. 1 is a diagrammatic perspective view of a tubular surgical implant according to the invention;

Fig. 2 is a detailed view of one end of the implant shown in Fig. 1;

Fig. 3 is a diagrammatic view of a blood vessel clamped and cut preparatory to engagement with the tubular surgical implant shown in Fig. 1;

Fig. 4 is a diagrammatic perspective view of the implant being inserted into the incision in the vessel;

Fig. 5 is a similar view to Fig. 4 showing the spikes of the implant being engaged; and

Fig. 6 is a similar view to Figs. 4 and 5 showing engagement of the locking ring.

MODES FOR CARRYING OUT THE INVENTION

In the preferred form of the invention a tubular surgical implant is provided for use as a by-pass between the aorta and a coronary artery although it will be appreciated that the device may be used in many other applications wherever it is necessary to join an artificial tube with a vessel or organ or to provide a by-pass between different vessels and/or organs. The implant is described as a double-ended device although it will be appreciated that in some applications the engagement flange and locking ring may be provided on one end of the tube only.

The implant comprises a tube (1) having a flange (2) at either end of the tube. The tube and flange may be formed from any suitable materials but are typically of a plastics mesh material such as a grade of Gortex (Registered Trade Mark) material which allows incorporation of human tissue and a long life for the device in the body.

Each flange is provided with a plurality of spikes

(3) extending from the flange, alongside and generally parallel to the tube (1). In this sense the spikes face away from the open end of the tube.

The implant is further provided with locking rings
5 (4) of the same general size and configuration of the flanges (2), the locking rings being arranged to slide axially on the tube (1). Each locking ring incorporates a plurality of holes (5) (Fig. 5) aligned with and adapted to receive the spikes (3) protruding from the
10 corresponding flange (2).

In order to ensure alignment of the holes (5) with the spikes (3) the locking ring may be keyed to the tube by way of a keyway (6) on the tube and a corresponding projection or aperture (not shown) in the locking ring
15 (4), preventing rotation of the ring relative to the tube. In this manner, the holes (5) can be accurately aligned with the spikes (3) enabling the ring to be engaged with the spikes as will be described further below.

The flange (2) is deformable relative to the tube
20 (1) either by deforming the entire flange relative to the tube so that the flange may lie against the tube for insertion into an opening of a vessel or organ, or alternatively the flange maybe deformable across one or
25 more hinge lines (7) (Fig. 2) allowing parts of the flange to bend back against the tube as shown in Fig. 4 for insertion into an opening in the wall of the vessel or organ.

The use of the implant will now be described with
30 reference to a typical coronary by-pass operation where the implant is engaged between the aorta and the distal coronary artery.

Referring to Fig. 3 the aorta (8) is first partially clamped by way of a non-traumatic clamp (9) positioned
35 partially across the aorta to allow the continuing flow of blood through unclamped portion (10). The clamped portion (11) of the aorta (8) may then be cut to form an incision (12) for engagement with the implant.

As shown in Fig. 4, the flange (2) may be deformed as previously described and inserted through the incision (12) until the entire flange is positioned within the aorta. The flange is then allowed or caused to open
5 behind the tissue wall of the aorta to its original configuration and the tube pulled back in the direction of arrow (13) (Fig. 5) engaging the spikes (3) through the tissue wall (11).

The locking ring (4) is then slid down the tube
10 until the spikes (3) are engaged with the holes (5) in the locking ring as shown in Fig. 6.

The spikes (3) and the holes (5) in the locking ring (4) are provided with a series of locking mechanisms arranged to retain the spikes within the holes when the
15 locking ring is engaged with the spikes as shown in Fig. 6. This locking mechanism may take any suitable configuration but is typically a series of "click into place" type of mechanism which engages the locking ring at various spacings from the flange to allow for several
20 aortic wall thicknesses.

The procedure may then be repeated at the other end of the implant to engage the other flange with the coronary artery so effectively and quickly providing a by-pass between the aorta and the coronary artery.

In the particular application of a heart by-pass operation the flange adapted to be engaged with the coronary artery may be smaller than the flange to be engaged with the aorta to suit the size of the vessel with which it is engaged. A range of different sized and
30 ended devices would be used to cover the range expected in different sized diameters and thickness of aortas and coronary arteries. In situations where there is more than one blockage in the coronary artery, the tubular surgical implant can be constructed as a manifold with
35 one larger aortic proximal end and several separate coronary distal ends. The tubes may be either parallel sided or tapered (conical) as required for the desired flow rates.

In this manner a surgical implant is provided which enables a coronary by-pass operation to be performed without stopping the heart function or the aorta blood flow to the body and which furthermore does not entail
5 the stripping of veins or arteries from other parts of the body to use as a by-pass conduit.

The implant has application in many other areas presently the province of vascular and microsurgery and may be used wherever it is necessary to join a tube to a
10 vessel or hollow organ or to form a connection between two vessels and/or organs.

CLAIMS:

1. A tubular surgical implant adapted to be joined to a wall of a vessel or hollow organ such that the implant opens into the interior of the vessel or organ, said
5 implant comprising an open ended tube, a deformable flange at one end of the tube, a plurality of spikes extending from the flange, alongside and generally parallel to the tube, and a locking ring arranged to slide axially on the tube, the locking ring incorporating
10 a plurality of holes aligned with and adapted to receive the spikes.
2. A tubular surgical implant as claimed in claim 1 wherein the locking ring is keyed to the tube, preventing rotation of the ring relative to the tube.
- 15 3. A tubular surgical implant as claimed in either claim 1 or claim 2 wherein the spikes and the holes in the locking ring are provided with a locking mechanism arranged to retain the spikes within the holes when the locking ring is engaged with the spikes.
- 20 4. A tubular surgical implant as claimed in any one of the preceding claims wherein the flange is deformable relative to the tube such that the flange may be deformed to lie against the tube for insertion into an opening in the wall of the vessel or organ.
- 25 5. A tubular surgical implant as claimed in any one of claims 1 to 3 wherein the flange is deformable across one or more hinge lines in the flange, allowing parts of the flange to bend back against the tube for insertion into an opening in the wall of the vessel or organ.
- 30 6. A tubular surgical implant as claimed in any one of the preceding claims wherein the implant is adapted to connect two vessels or hollow organs and is provided with a flange and locking ring at both ends of the tube.
- 35 7. A tubular surgical implant as claimed in any one of the preceding claims wherein the tube and the flange are made of a plastics mesh which allows for incorporation of human tissue.
8. A method of connecting two vessels or hollow organs

by way of a surgical implant, comprising the steps of:
providing a tubular surgical implant adapted to be joined
to a wall of a vessel or organ such that the implant
opens into the interior of the vessel or organ, said
5 implant comprising an open ended tube, a deformable
flange at one end of the tube, a plurality of spikes
extending from the flange, alongside and generally
parallel to the tube, and a locking ring arranged to
slide axially on the tube, the locking ring incorporating
10 a plurality of holes aligned with and adapted to receive
the spikes; cutting a hole or slit in the tissue wall of
the first vessel or organ, inserting the end of the tube
into the hole or slit with the flange deformed, allowing
or causing the flange to open behind the tissue wall,
15 engaging the spikes through the tissue wall and sliding
the locking ring on the tube until the spikes are engaged
with the holes in the locking ring.

9. A method as claimed in claim 8 wherein the area of
the first vessel or organ surrounding the hole or slit is
20 isolated from the remainder of the first vessel or organ
by way of a clamp before making the hole or slit, in a
manner allowing fluid to continue to flow through the
remainder of the vessel or organ.

10. A method as claimed in either claim 8 or claim 9
25 wherein the first vessel or organ comprises an aorta and
the second vessel or organ comprises a distal coronary
artery.

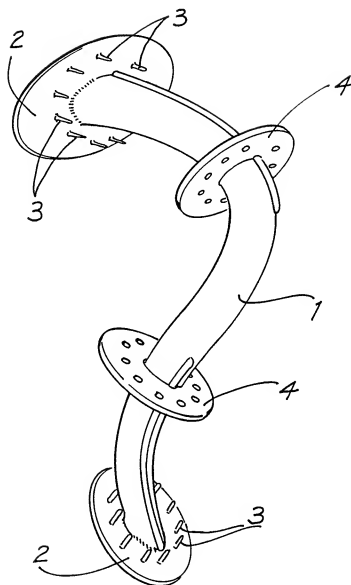
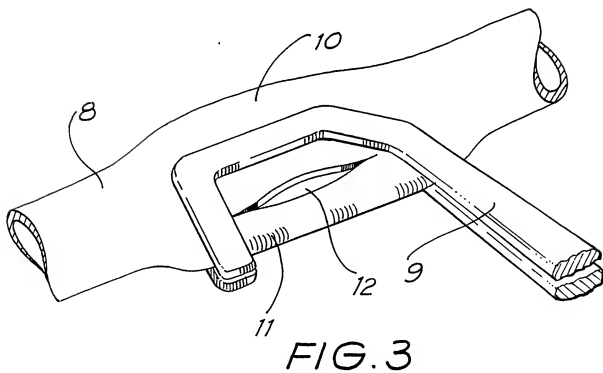
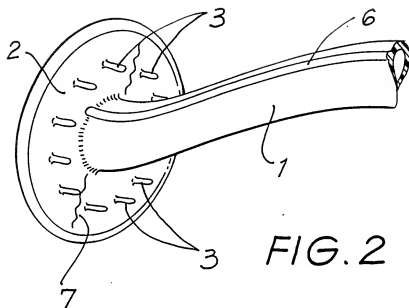
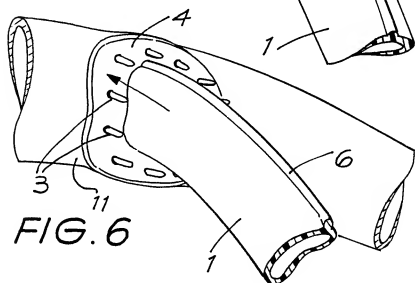
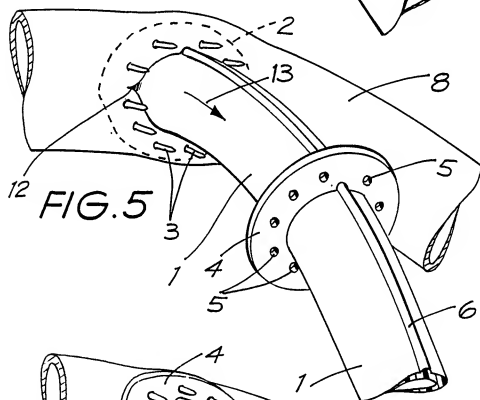
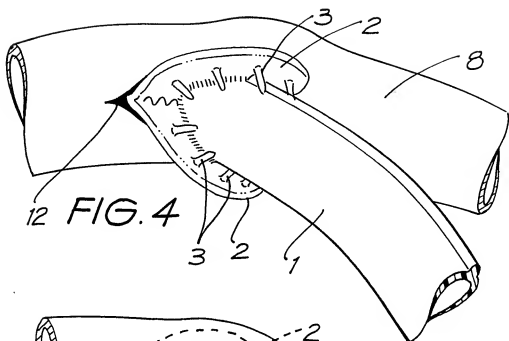


FIG. 1



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INTERNATIONAL SEARCH REPORT

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all)⁶

According to International Patent classification (IPC) or to both National Classification and IPC
Int. Cl.⁶ A61F 2/06

II. FIELDS SEARCHED

Minimum Documentation Searched⁷

Classification System

Classification Symbols

IPC A61F 2/06 A61F 1/00

Documentation Searched other than Minimum Documentation
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AU : IPC as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹

Category [*]	Citation of Document, ¹¹ with indication, where appropriate of the relevant passages ¹²	Relevant to Claim No ¹³
A	WO,A, 90/15582 (TROUT) 27 December 1990 (27.12.90)	
A	WO,A, 88/06865 (BIEMANS) 22 September 1988 (22.09.88)	
A	EP,A, 0269254 (ETHICON INC et al) 1 June 1988 (01.06.88)	
A	SU,A, 1593651 (MOSC MED SKCHENOV) 23 September 1990 (23.09.90) Derwent Abstract Accession no. 91-154896/21 Class P 32	

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IV. CERTIFICATION

Date of the Actual Completion of the International Search
12 August 1992 (12.08.92)

Date of Mailing of this International Search Report

31 Aug. 1992 (31.08.92)

International Searching Authority

Signature of Authorized Officer

AUSTRALIAN PATENT OFFICE

A. DAVIES

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON
INTERNATIONAL APPLICATION NO. PCT/AU 92/00328

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member			
SU	1593651				
EP	269254	AU 80150/87 US 4883453	BR 8705699 ZA 8708026	JP 63158052	
WO	9015582	AU 58589/90	CA 2033195	EP 429629	
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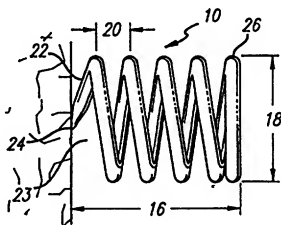
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/US95/07270 (22) International Filing Date: 7 June 1995 (07.06.95) (30) Priority Data: 08/286,878 5 August 1994 (05.08.94) US (71) Applicant: ORIGIN MEDSYSTEMS, INC. [US/US]; 135 Constitution Drive, Menlo Park, CA 94025 (US). (72) Inventors: BOLDUC, Lee; 761 - 1/2 Palo Alto Avenue, Mountain View, CA 94041 (US). KRAMER, Thomas, A.; 1149 Orange Avenue, San Carlos, CA 94070 (US). HODGES, Brian, A.; 360 Sunfish Court, Foster City, CA 94404 (US). McCOY, Tim; 2 Cottage Lane, San Carlos, CA 94070 (US). LUNSFORD, John; 3378 Brittan Avenue #15, San Carlos, CA 94070 (US). (74) Agent: FULWIDER PATTEN LEE & UTECHT; 10th floor, 10877 Wilshire Boulevard, Los Angeles, CA 90024 (US).		(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: SURGICAL HELICAL FASTENER WITH APPLICATOR

(57) Abstract

A helical fastener (10) having a high retentive surface area is provided and has a first end (22) for enhancing penetration into tissue (25) and a second end (26) comprising a coil sectioning a diameter (18) of the fastener (10) for receiving longitudinal and rotational forces. The helical fasteners (10) are attached to body tissue (25) by a fastener applicator (12) having a proximal portion (28) comprising a handle (30) and an actuator (32) and an elongate distal portion (34) for housing a plurality of fasteners (10). A transferring action of the actuator (32) provides longitudinal and rotational movement of the fasteners (10) out of the distal portion (34) and into body tissue (25).



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SURGICAL HELICAL FASTENER WITH APPLICATOR

BACKGROUND OF THE INVENTION

This invention relates to surgical fasteners and their associated applicators, and more particularly, surgically fastening material to tissue.

Fasteners have been used surgically to eliminate the need for suturing, which is both time consuming and inconvenient. In many applications the surgeon can use a stapler apparatus, i.e., a fastener implanting device loaded with surgical fasteners to accomplish in a few seconds what would have taken many minutes to perform by suturing. This reduces blood loss and trauma to the patient.

Conventional surgical fasteners have been in the form of ordinary metal staples, which are bent by the delivery apparatus to hook together body tissue. Typically, conventional staples comprise a pair of legs joined together at one end by a crown. The crown may be a straight member connecting the legs or may form an apex. Moreover, the legs may extend substantially perpendicular from the crown or at some angle therefrom. Irrespective of the particular configuration, however, conventional staples are designed so that they may be deformed to hold body tissue.

Accordingly, the stapler applicators have conventionally embodied structure functioning to project the conventional staple into tissue as well as to deform the staple so that it is retained against the tissue. Generally speaking, typical applicators include an anvil cooperating with means to eject the conventional staple from the applicator. In some applications, access to the body tissue from two opposite directions is available and the anvil can operate to deform the legs of the staple after they have passed through the body tissue. In applications where access to the tissue is from only one direction,

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the anvil may deform the crown of the conventional staple so that its legs will project into the body tissue in a fashion so as to hold the staple against the tissue.

- 5 Since conventional staples require deformation and must cooperate with applicators having an anvil or other means to deform the staples, conventional applicators typically comprise complex structures and can be prohibitively expensive.
- 10 Conventional applicators must embody structure functioning to not only eject the fasteners but to do so in a manner so that the fastener deforms properly and timely.

- In some applications, conventional
- 15 applicators must be equipped with structure functioning to move the anvil into and out of position so that when the fastener is ejected from the applicator, the anvil is properly positioned and once fastener deformation is complete, moves out of position, thereby allowing the
- 20 process to be repeated. Moreover, the anvil must be formed into a proper configuration so that fastener deformation can be repeated accurately. Further, the force between the fastener and the anvil must be controlled so that repeated deformation is
- 25 accomplished. The objectives of many inventions in this field have been to accomplish these goals by the simple manipulation of a single lever. It is to be appreciated, therefore, that the fastener applicators have become complex and expensive instruments.

- 30 Two part fasteners have also been conventionally utilized, where a barbed staple is used in conjunction with a retaining piece to hold the staple in place. Typically, the two part staple comprises a crown or backspan and two barbed prongs
- 35 which are engaged and locked into a separate retainer piece. In use, the staple is pressed into the body tissue so that the barbs penetrate the tissue and

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emerge from the other side where they are then locked into the retainer piece. Retainers prevent the staple from working loose from the tissue. The two piece fasteners cannot be unlocked and are not removable.

5 Like other conventional applications, however, the two piece fasteners require the staple delivery apparatus to have access to both sides of the tissue. Thus, as with the other conventional applications, two piece fasteners are limited since
10 they cannot be used where access to tissue is from one direction only.

 In those situations where access to body tissues is limited to one direction, as in grafting procedures, deformable surgical fasteners have been
15 conventionally employed. As mentioned previously, however, the applicators commonly used in these situations embody an anvil cooperating with a fastener to deform it and consequently, tend to be of a complex design.

20 Some advancements have been made in this area so that applicators functioning to attach grafts to tissue, for instance, are not required to embody an anvil and may, therefore, have a more simple design. In particular, it has been suggested in the art to
25 employ fasteners with barbs, thereby eliminating the need for deforming the fastener. These fasteners are limited, however, since the path created in the graft and tissue by the barbs as the fastener is pressed into the graft and tissue may allow the fastener to loosen
30 its grip or to entirely back out of engagement. Moreover, due to their sole reliance upon barbs to retain tissue, the barb fasteners are further limited in that they may not have a great enough retentive surface area for securely holding tissue in place.

35 To circumvent or overcome the problems and limitations associated with conventional fasteners and applicators, a simple applicator that dispenses a

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surgical fastener having high surface area for retentive contact with tissue and that can be delivered into body tissue from one direction may be employed. The present invention embodies these characteristics.

5

SUMMARY OF THE INVENTION

The invention includes a surgical fastener and an applicator used in delivering the fastener into body tissue. The fastener and applicator of the present invention may be used in a number of medical procedures including ligating tissue, hernia mesh repair, bladder neck suspension, and in conjunction with implant drug delivery systems or procedures involving positioning of surgical or implantable devices in a patient's body.

15 The preferred embodiment of the surgical fastener of the present invention is formed into the configuration of a continuous helical coil. The continuous helical coil is longitudinally collapsible and expandable. At the distal end of the helical fastener is a point for enhancing penetration into tissue. The proximal end of the helical fastener has a T-bar which sections the diameter of the fastener, thereby providing a surface for receiving and transmitting longitudinal and rotational forces so that the fastener may be driven into tissue by a corkscrew action. The pitch and length of the helical fastener may vary upon the application as can its diameter and configuration of the most proximal and distal coils comprising the fastener. Additionally, the material selection and fastener stiffness may be selected with a particular application in mind.

25 In another embodiment of the surgical fastener, the fastener comprises a double continuous helical coil that is also longitudinally collapsible and expandable and may embody various configurations

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depending upon the application. Moreover, the distal end of the double helical fastener comprises two points for enhancing penetration into tissue and its proximal end comprises a connector bar which connects the two
5 helixes as well as sections the diameter of the double helical fastener. In yet another embodiment, the surgical fastener further comprises a pivot post extending through the center of the fastener and operating to provide the fastener with a stable pivot.
10 In any of the embodiments, one or more barbs may be employed near the point to enhance anchoring characteristics.

A preferred embodiment of the fastener applicator of the present invention includes a proximal portion and a distal portion. The proximal portion is preferably fabricated to be a "reusable" component and the distal portion a "disposable" component.
15 Alternatively, both the distal and proximal portion can be made disposable. The distal portion is elongate and embodies an outer tube housing an inner rotator, a lock clip/indicator and a load spring. The proximal portion includes a handle. In the preferred embodiment of the distal portion, a thread form comprising an interlock spring is provided within the outer tube. The rotator
20 includes a structure running longitudinally along its length that functions to receive the T-bar or connector bar of the fastener and in this way, the rotator may hold a plurality of fasteners. The load spring applies a force against the lock clip/indicator operating to bias the plurality of springs distally within the outer tube and towards the nose piece. The thread form functions to engage the coils of the helical fasteners and when rotating the rotator, a fastener is driven from the distal end of the applicator. In other
25 embodiments of the applicator, the distal end has various other structures functioning to engage the coils of the fastener and to drive them from the distal
30
35

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end of the applicator. In one other embodiment, the distal end comprises a nose piece protrusion for engaging the fastener.

In order to cause the rotator to rotate, the proximal portion of the applicator has a handle and an actuator cooperating with the rotator. In a preferred embodiment, the proximal portion of the applicator embodies a lever pivotally attached about a midpoint to the handle. A first end of the lever is configured to be gripped by hand and a second end is adapted to engage a nut driver. The nut driver travels along a helical lead screw which is connected to the rotator. When the lever is squeezed by hand the nut driver travels along the lead screw causing it to rotate, and through the connection of the lead screw to the rotator, the action of the lead screw causes the rotator to rotate.

Further, the lever comprises a midsection extension. Pivotaly attached to the midsection extension of the lever is a spring loaded pawl adapted to releasably engage gear teeth formed in the interior of the handle. The spring loaded pawl prohibits the lever from backstroking until it has been completely depressed. Upon complete depression of the lever, the pawl clears the gear teeth and the spring, biasing the pawl, rotates the pawl away from the teeth, thereby allowing the lever to return to its undepressed condition.

In another embodiment of the proximal portion of the applicator, the lever is pivotally attached at a first end to the handle, the second end being adapted to engage the nut driver. Further, rather than embodying a spring loaded pawl, this alternate embodiment of the proximal portion includes a clutch assembly or releasable connection between the lead screw and rotator and cooperating means to prohibit the

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lever from backstroking until it has been completely depressed.

Other features and advantages of the present invention will become apparent from the following
5 detailed description, taken in conjunction with the accompanying drawings, which illustrate, by way of example, the principals of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 depicts a perspective view of a fastener of the present invention, illustrating a side view of a helical fastener.

5 FIG. 1A depicts another perspective view of the fastener of the present invention, illustrating an end view of the helical fastener.

 FIG. 1B depicts a schematic view of a fastener of the present invention, illustrating a
10 substantially collapsed helical fastener with a relatively small gap that has been partially inserted into tissue.

 FIG. 1C depicts a schematic view of a fastener of the present invention, illustrating the
15 helical fastener depicted in FIG. 1B completely inserted into tissue.

 FIG. 1D depicts a schematic view of a fastener of the present invention, illustrating a
20 substantially collapsed helical fastener with a relatively large gap that has been partially inserted into the tissue.

 FIG. 1E depicts a schematic view of a fastener of the present invention, illustrating the
25 helical fastener depicted in FIG. 1D completely inserted into tissue.

FIG. 1F depicts a perspective view of another embodiment of the present invention, illustrating an end view of the helical fastener.

FIG. 2 depicts a perspective view of another embodiment of the present invention, illustrating a
5 double helical fastener.

FIG. 2A is a front view of the double helical fastener of FIG. 2.

FIG. 2B is side view of the double helical
10 fastener of FIG. 2.

FIG. 2C is a top view of the double helical fastener of FIG. 2.

FIG. 3 is a perspective view of yet another embodiment of the present invention, illustrating
15 another design of a double helical fastener.

FIG. 3A is a front view of the double helical fastener of FIG. 3.

FIG. 3B is a side view of the double helical fastener of FIG. 3.

FIG. 3C is a top view of the double helical fastener of FIG. 3.
20

FIG. 4 is a perspective view of the present invention, illustrating a helical fastener with a central post.

FIG. 5 depicts a schematic cross-sectional view of an applicator of the present invention, illustrating a side view of the applicator.
25

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FIG. 6 is a schematic cross-sectional side view of a terminal end of the applicator.

FIG. 6A is a schematic cross-sectional end view of a terminal end of the applicator.

5 FIG. 7 is a schematic cross-sectional view of the terminal end of the applicator, illustrating the preferred embodiment of the terminal end.

 FIG. 7A is a schematic cross-sectional end view of the preferred embodiment of the terminal end of
10 the application shown in FIG. 7.

 FIG. 8 is a schematic cross-sectional view of the terminal end of the applicator, illustrating another embodiment of the terminal end.

 FIG. 8A is a schematic cross-sectional end
15 view of the embodiment of the terminal end of the applicator shown in FIG. 8.

 FIG. 9 is a schematic cross-sectional view of the terminal end of the applicator, illustrating yet another embodiment of the terminal end.

20 FIG. 9A is a schematic cross-sectional end view of the embodiment of the terminal end of the applicator shown in FIG. 9.

 FIG. 10 is a schematic cross-sectional view of the terminal end of the applicator, illustrating
25 still yet another embodiment of the terminal end.

 FIG. 10A is a schematic cross-sectional end view of the embodiment of the terminal end of the applicator shown in FIG. 10.

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FIG. 11 is a schematic cross-sectional view of the terminal end of the applicator, illustrating another embodiment of the terminal end.

FIG. 11A is a schematic cross-sectional end view of the embodiment of the terminal end of the applicator shown in FIG. 11.

FIG. 12 is a schematic cross-sectional view of the terminal end of the applicator, illustrating a further embodiment of the terminal end.

FIG. 12A is a schematic cross-sectional end view of the embodiment of the terminal end of the applicator shown in FIG. 12.

FIG. 13 is a schematic cross-sectional view of the terminal end of the applicator, illustrating a still further embodiment of the terminal end.

FIG. 14 is a schematic cross-sectional view of the terminal end of the applicator, illustrating still yet another embodiment of the terminal end.

FIG. 15. is a schematic cross-sectional view of another applicator of the present invention, illustrating a side view of the applicator.

FIG. 16 is a schematic partial cross-sectional view of a releasable connection between the lead screw and rotator.

FIG. 16A is schematic representation of a distal end of the lead screw, illustrating an end view of the lead screw.

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FIG. 16B is a schematic representation of the distal end of the lead screw, illustrating a side view of the lead screw depicted in FIG. 16.

FIG. 16C is a schematic representation of the proximal end of the rotator, illustrating a side view
5 of the rotator.

FIG. 16D is a schematic representation of the proximal end of the rotator, illustrating an end view of the rotator depicted in FIG. 16B.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As is shown in the drawings, which are included for purposes of illustration and not by way of limitation, the invention is embodied in a continuous helical fastener and an applicator therefor. The helical fastener has a high retentive surface area and the applicator has a simple design and functions to dispense the helical fasteners, without substantially deforming the fasteners, into body tissue, access to which is from one direction only. Some conventional fasteners require deformation to hold tissue and are consequently limited since they require complex applicators to attach them into tissue. Other conventional fasteners lack high retentive surface area for securely holding tissue. Still other fastener/applicator systems require access to tissue from two directions in order to accomplish attaching a fastener to tissue. Thus, the helical fastener and applicator of the present invention provides a superior means to attach fasteners to tissue.

One embodiment of the present invention (FIGS. 1, 1A and 5) is embodied in a helical fastener 10 which is attached to tissue by employing a novel applicator 12 which rotates the fastener 10 into tissue. The dimensions and physical characteristics of the helical fastener 10 are selected to insure a secure attachment of the fastener 10 to tissue. Similarly,

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the dimensions and physical characteristics of the applicator 12 utilized to dispense the fasteners 10 into tissue are dependent upon the application.

In a preferred embodiment, the fastener 10 is
5 formed into the configuration of a continuous helix and may have a depth 16, a diameter 18 and a pitch 20 determined by the application. The continuous helix may be longitudinally collapsible and expandable. The cross-sectional profile of the continuous helix is
10 substantially circular in the preferred embodiment but can be square, rectangular or triangular. In a particular application such as mesh anchoring for hernia repair, the pre-formed pitch can be .050 inches. However, the pre-formed pitch can vary from 0 to a
15 maximum of approximately 3.0 times the coil diameter. In other embodiments, it is contemplated that the pitch 20 vary along the length of the fastener 10 so as to optimize the retaining force of the fastener 10. Moreover, since the continuous helical coil is
20 preferably longitudinally collapsible and expandable, upon insertion into tissue, the final pitch 31 may be less than or greater than the pre-formed pitch. If the coil is made of rigid construction, as is also contemplated, pitch would be made substantially fixed.
25 The diameter in the preferred embodiment may be 5 mm; however, designs ranging from 1 mm and up are contemplated. In practice, the depth 16 of the fastener 10 must be selected so that the extent of

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fastener penetration into tissue is sufficient to hold the fastener 10 in place.

Moreover, distal end 22 of the fastener 10 is to be configured such that a gap 23 exists between the most distal coil 27 (or first coil) of the fastener 10 and its adjacent coil. As may be appreciated from the preferred embodiment of FIGS. 1B through 1E, as the fastener 10 is pressed against tissue 25, all of the coils substantially collapse except the most distal coil 27, leaving the gap 23 to determine the path the fastener 10 takes as it is rotated into the tissue 25 and more importantly, the extent of penetration 29 into the tissue 25 and final pitch 31 of the fastener 10 in tissue. Although FIG. 1B shows substantially all of the coils being collapsed, it is to be appreciated that, depending upon the applicator utilized to implant the fastener 10, fewer coils than all of the coils may be collapsed at any one time. It remains, however, that since the fastener 10 is longitudinally collapsible and expandable, it is the gap 23 that generally determines final pitch 31. Accordingly, the magnitude of the gap 23 can be varied, depending upon the application, to achieve the desired final pitch 31 and penetration 29 in tissue. Thus, the greater the gap 23, upon insertion of the fastener 10 in tissue, the greater the penetration 29 and final pitch 31 of the fastener 10 in tissue.

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In the preferred embodiment, the distal end 22 of the helical fastener 10 terminates with a point 24. The point 24 may be sharp or blunt depending upon the tissue to which the fastener 10 will be affixed.

5 Additionally, one or more barbs or a sharp point projecting in reverse direction to point 24 (not shown) can be added to fastener 10 near point 24 to enhance anchoring characteristics of the fastener. A proximal end 26 of the helical fastener 10 may comprise

10 structure functioning to receive and transmit applied longitudinal forces. In the preferred embodiment, the most proximal coil is formed into a T-bar 33 that perpendicularly sections the diameter 18 of the fastener 10. In alternate embodiments, it is also

15 contemplated that the most proximal coil section the diameter 18 non-perpendicularly or be formed into a spiral 35 existing in a single plane (See FIG. 1F).

Concerning the material of the helical fastener 10, it is contemplated in the preferred

20 embodiment that the fastener be made from semi-stiff implantable wire, such as titanium, wound into a helical shape. In alternate embodiments, the helical fastener 10 may comprise plastic or absorbable materials. Examples of materials that can be used in

25 constructing the helical fastener 10 include titanium, titanium alloys, stainless steel, nickel, chrome alloys and any other biocompatible implantable metals. Other options for materials are liquid crystal polymers,

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HDPE, polyglycolic acid, and polyglycolid hydroxycacetic acid. Further, it may also be desirable to coat the fastener, or a portion thereof, with a biocompatible lubricious material that provides for easier delivery of the fastener into tissue.

In another embodiment of the surgical fastener, the fastener 110 is formed into the configuration of a double helix (See FIGS. 2-2C). By embodying a double helix, the fastener 110 has increased retentive strength as well as means to balance the fastener 110 as it is pressed into tissue. As with the helical fastener 10, the configuration of the double helical fastener 110, i.e., the pre-formed pitch and diameter, may be varied for a particular application and a barb may be employed to enhance anchoring in tissue. Moreover, the materials contemplated are the same as those for the helical fasteners. Further, the double helical fastener 110 is also longitudinally collapsible and expandable and its final pitch is dependent upon the gap 112 existing between the most distal coils 114, 115 of the fastener 110 and their adjacent coils.

Regarding the proximal 118 and distal 120 ends of the double helical fastener 110, they comprise structure to drive the fastener into tissue as well as tissue piercing structures. The proximal end 118 has a connector bar 122 sectioning the diameter of the fastener that connects one helical coil to another and

-18-

functions to receive and transmit longitudinal forces. The distal end 120 terminates with two points 124, 125 for piercing and facilitating the implantation of the fastener 110 into tissue.

5 As may be appreciated by comparing FIGS. 2-2D with FIGS. 3-3D, it is contemplated that the double helical fastener 110 have a full turn design (FIGS. 2-2D) as well as a half turn design (FIGS. 3-3D). It is to be understood, however, that the designs having more
10 than one turn and having other increments of turns are contemplated. It is the applicator that will determine the required number of turns for a specific fastener 110.

 In yet another embodiment of the surgical
15 fastener, as shown in FIG. 4, the double helical fastener 110 is provided with a pivot post 130 having a pointed terminal end 132. The pivot post 130 of this embodiment operates to provide the fastener 110 with a stabilizing element so that, as the fastener 110 is
20 being turned, the helical coils cooperatively enter the tissue.

 The applicator 12 (FIG. 5) comprises a proximal portion 28 having a handle 30 and an actuator 32 and a cooperating elongated distal portion or
25 cannula 34 housing a plurality of fasteners. In general, through the manipulation of the actuator 32, the fasteners are ejected, one by one, out of a distal portion 34 and into body tissue. The applicator 12,

hereinafter described in more detail, is equally proficient in driving each of the embodiments of fasteners set forth above into tissue.

In more detail (see FIGS. 6 and 6A), the distal portion 34 comprises an outer tube 36 housing a rotator 38, a lock/clip indicator 40 and a load spring 42. Extending longitudinally along the rotator 38 is a groove 44 which operates to receive the most proximal coil sectioning the fastener. Although FIG. 6 shows only a single fastener (having a single helical design) retained by the rotator 38, it is to be appreciated that the rotator 38 may receive a plurality of fasteners (having a single or double helical design), wherein each fastener has its last coil positioned within the rotator groove 44. Moreover, although not depicted in FIG. 3, it is also contemplated that rather than embodying a groove, the rotator 38 has a cross-sectional profile approximately a "D", wherein the flat portion operates to engage the coil sectioning the fasteners. Irrespective of the configuration of the rotator, however, the rotator is to embody structure functioning to engage a plurality of fasteners and to facilitate turning them into tissue.

It is also to be appreciated that load spring 42 applies a force through the lock clip indicator 40 to bias the plurality of fasteners distally. The lock clip/indicator 40 may comprise a simple washer sized and shaped to engage the fasteners and rotator 38 as

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well as to receive forces from the load spring 42. Additionally, lock/clip indicator 40 serves as a jam stop to prevent further actuation by rotator 38 upon discharge of all fasteners by mating with, or abutting against, structure comprising the terminal end 50 and preventing further rotation. Lock/indicator 40 can be made of a color (or shape) to serve as an empty indicator notifying the user that no more fasteners are available. Other embodiments of the indicator 40 may be utilized as long as they function to transmit forces to bias the fasteners distally. The load spring 42 is to be retained within the outer tube 36 and to have physical characteristics such that sufficient forces may be applied through a front end 43 to a last remaining fastener contained within the applicator 12. A back end (not shown) of the load spring 42 may be placed against any stationery structure within the outer tube 36, thereby providing a foundation against which the spring 42 may be compressed. In a preferred embodiment, the load spring 42 extends substantially the length of the distal portion 34.

In the preferred embodiment (FIGS. 7 and 7A), the outer tube 36 is configured with a thread form 201 comprising an interlock spring 203 fixedly retained within the outer tube 36 and extending substantially the length thereof. The interlock spring 203 may be fixedly retained within the outer tube 36 by ensuring a tight interference between the parts or the interlock

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spring may be spot welded or equivalently bonded within the outer tube. The thread form 201 operates to guide the fasteners through the distal portion 34 and to eject them from the applicator 12.

5 In another embodiment of the applicator 12 (FIGS. 8 and 8A), attached at a terminal end 46 of the distal portion 34 may be a nose piece 48. The nose piece 48 may further comprise a protrusion 50 extending perpendicularly and towards a longitudinal axis 52 of
10 the distal portion 34. This nose piece protrusion 50 also functions to engage the surgical fasteners and to force them from the terminal end 46 of the distal portion 34 as well as engaging lock/clip indicator 40 as described above.

15 In other embodiments of the applicator 12, the distal portion embodies other structure or thread forms functioning to engage the surgical fasteners and guide them out of the applicator and into tissue (See FIGS. 9-14). In FIGS. 9 and 9A, the outer tube 36 is
20 rolled at its terminal end 46 and a 180° portion of the rolled terminal end is cut away. The remaining rolled portion engages the fastener while the portion cut away provides an exit for the fasteners. The embodiment depicted in FIGS. 10 and 10A is similar to that of
25 FIGS. 9 and 9A, the difference being that instead of removing a portion of the rolled terminal end 46, it is stamped or deformed to thereby provide an exit. FIGS. 11 and 11A show yet another embodiment, wherein two

-22-

longitudinally spaced apart stabilizing points 301, 302 are formed 180° from each other within the outer tube. These stabilizing points also operate to engage the fastener and guide it into tissue. Turning to FIGS. 5 12, 12A, 13 and 14, they each comprise a terminal end 46 formed with threads which operate to engage and eject a fastener. In FIGS. 12 and 12A are depicted threads machined or formed solely within the inside of the outer tube. FIG. 13 shows an internally threaded 10 sleeve attached to the outside of the terminal end 46 of the outer tube 36. FIG. 14 illustrates an applicator 12 provided with a terminal end 46 deformed so as to have internal and external threaded structures. Irrespective of the design chosen for the 15 terminal end of the applicator, however, each of the designs are effective with a relatively small overall outer diameter, i.e., on the order of 5mm.

In order to eject surgical fasteners from the distal portion 34, the actuator 32 functions to turn 20 the rotator 38. As the rotator turns, the distal end 22 of a fastener is threaded out of the terminal end 46 of the applicator 12 (see FIG. 5).

In the preferred embodiment of the proximal portion 28 of the applicator 12 (See FIG.5), a lever 54 25 is pivotally connected about a midpoint 56 to the handle 30. A first end 58 of the lever 54 is to be configured for gripping by hand. A second end 60 of

-23-

the lever is to be adapted to pivotally engage a nut driver 62.

The nut driver 62 of the applicator 12 travels upon a high helix lead screw 64 which is

5 rotatably mounted within the proximal portion 28. In the preferred embodiment, a longitudinal axis of the high helix lead screw 64 is coaxial with the longitudinal axis 52 extending through the distal

10 portion 34 of the applicator 12. Upon manipulation of the lever 54, the nut driver 62 travels along the lead screw 64 causing it to rotate through a connection of the lead screw 64 to the rotator 38, the action of the lead screw causes the rotator to rotate. The lead screw 64 may be connected to the rotator 38 by any

15 conventional means. For instance, the lead screw 64 can have an internal bore receiving and engaging an end of the rotator 38. Further, the length of travel of the nut driver 62 along the lead screw 64 is chosen such that it causes the rotator to rotate a

20 predetermined number of times so that a single helical fastener 10 is ejected from the applicator 12.

Additionally, in the preferred embodiment, the lever further comprises a midsection extension 66. Pivottally attached to the midsection extension 66 of

25 the lever 54 is contemplated to be a spring loaded pawl 68 adapted to releasably engage gear teeth 70 formed in the interior of the handle 30. Spring loaded pawl 68 is configured to prohibit the lever 54 from

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backstroking until it has been completely depressed. Upon complete depression of the lever 54, the pawl 68 clears the gear teeth 70 and the spring biasing the pawl 68 rotates the pawl 68 away from the teeth 70, thereby allowing the lever 54 to return to its undepressed condition.

In operation, upon complete depression of the lever 54, the nut driver 62 travels a pre-determined distance along the lead screw 64, causing the rotator 38 to rotate a pre-determined number of revolutions corresponding to a number of turns of a particular helical fastener 10. As the rotator 38 rotates, the fasteners retained by the rotator also rotate and the coils of the most distal fastener are threaded out of the terminal end 46 of the applicator 12 and into tissue. Moreover, where the lever 54 is only partially depressed, the spring loaded pawl 68 operates to hold the lever 54 stationery and will continue to function to hold the lever 54 stationery until the lever 54 has been completely depressed. In this way, the delivery of fasteners into body tissue is controlled so that only a single fastener may be completely ejected out of the applicator 12 and pressed into body tissue at a time.

In the preferred embodiment, the proximal portion 28 is fabricated to have a reusable handle that can be re-sterilized, and the distal portion is made disposable. Thus, upon discharge of all the fasteners

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10 from distal portion 34, the distal portion would be discarded and replaced. The handle could be reused up to a limited number of procedures.

In another embodiment of the proximal portion
5 328, of the applicator 312 (FIG. 15), a lever 354 is pivotally connected at a first end 355 to the handle 330 and biased to its undepressed position by a spring 357. The mid-section 358 of the lower 354 is configured for gripping by hand. A second end 360 of
10 the lever is to be adapted to pivotally engage a nut drive 362.

The nut driver 362 of the applicator 312 travels along a high helix lead screw 364 which is rotatably mounted within the proximal portion 328.
15 Upon manipulation of the lever 354, the nut driver travels along the lead screw 364 causing it to rotate and, through a clutch assembly or a releasable connection of the lead screw 364 to the rotator 38, the action of the lead screw causes the rotator to rotate.

20 Further, the lever 354, has a mid-section extension 366 that cooperates with a spring biased latch pawl mechanism 368 fixed to the handle adapted to releasably engage teeth 370 formed on the mid-section extension 366. The spring biased latch pawl is
25 configured to prohibit the lever 354 from backstroking until it has been completely depressed. Upon complete depression of the lever 354, the latch pawl 368 clears the mid-section teeth 370 and the spring biased latch

-26-

pawl 368 rotates away from the teeth, thereby allowing the lever 354 to return to its undepressed condition.

As stated, there is a releasable connection between the lead screw 364 and the rotator. The

5 releasable connection provides the applicator with means to disengage the distal portion of the applicator from the proximal portion. In this way, the proximal portion can be re-used with various different designs of the proximal portion. Further, while the lever 354

10 is being depressed, the clutch assembly or releasable connection functions to transfer the rotation of the lead screw 364 to the rotator 38, thereby causing the rotator to rotate. Additionally, upon complete

15 depression of the lever, the clutch assembly operates to allow relative motion of the lead screw 364 and the rotator.

One such releasable connection contemplated is a conventional ratchet mechanism. As shown in FIGS. 16-16D, the distal end 370 of the lead screw 364 has a

20 connecting surface 372 equipped with leaf springs 374, 376 each having an engaging face 377 and an internal bore 378 existing coaxially with a longitudinal axis of the lead screw. The proximal end 380 of the rotator 38 has a cooperating connecting surface 382 having ridges

25 384 for releasable engagement with the leaf springs 374, 376 and an extension 386 adapted to fit within the internal bore of the lead screw connecting surface. As may be appreciated from the FIGS., as the lead screw

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turns so that the ridges 384 contact the engaging faces 377 of the leaf springs 374, 376, the rotation of the lead screw 364 will cause the rotator 38 to likewise rotate. Where the lead screw is turned in the opposite
5 direction, the ridges 384 will not engage the engaging face of the leaf springs and the motion of the lead screw 384 will not be transferred to the rotator 38.

In this embodiment, upon complete depression of the lever 354, the nut driver 362 travels a pre-determined distance along the lead screw 364, causing
10 the rotator 38 to rotate a pre-determined number of revolutions. As the rotator 38 rotates, the fasteners retained by the rotator also rotate and the coils of the most distal fasteners are threaded out of the
15 applicator and into the tissue. At this point, the latch pawl mechanism 368 disengages from the teeth 370 and the lever 354 is returned to its undepressed position by spring 357. As with the previous
embodiment of the proximal portion 28, the proximal
20 portion of this embodiment functions to allow only a single fastener to be completely ejected from the applicator and be pressed into body tissue at a time.

In other embodiments, means to cause the rotator to rotate may comprise a single knob connected
25 to a rotator which can be turned by hand. Additionally, the revolving means may include a rack and gear structure or a set of beveled gears. Further, instead of comprising a groove, the rotator may be

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internally threaded, wherein the threaded portions function to house as well as advance the helical fasteners 10. Irrespective of the means or structure employed, however, it is contemplated that the number
5 of revolutions of the rotator be set to a pre-determined parameter so that the delivery of helical fasteners to tissue may be controlled.

From the foregoing, it will be appreciated that the helical fastener in applicator of the present
10 invention functions to securely attach a fastener with high retentive surface area to tissue from one direction through the utilization of an applicator having a simple design. It is also to be appreciated that the present invention may be utilized in a number
15 of applications including ligating tissue, hernia mesh repair, bladder neck suspension, and in conjunction with implant drug delivery systems or procedures involving positioning of surgical or implantable devices in patient.

20 While several particular forms of the invention have been illustrated and described, it will also be apparent that various modifications can be made without departing from the spirit and scope of the invention.

25 Thus, it should be understood that various changes in form, detail and application of the present invention may be made without departing from the spirit and scope of this invention.

WHAT IS CLAIMED IS:

1. A fastener for ligating tissue or attaching an implantable device, the fastener comprising:

5 a continuous helical coil having a distal end and a proximal end;

a first helical coil section at said distal end;

tissue piercing means on said first coil; and

10 means for inserting said continuous helical coil so that said continuous helical coil penetrates tissue to ligate the tissue to position and attach the implantable device.

2. The fastener of claim 1, wherein said tissue piercing means is a point formed at a terminal end of said first helical coil section.

3. The fastener of claim 2, wherein said point of said first helical coil section and an adjacent coil section define a gap, said gap adapted to determine depth of penetration and pitch of the
5 fastener in tissue and retentive strength of the fastener to tissue.

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4. The fastener of claim 1, wherein said continuous helical coil has a uniform pitch between coils.

5. The fastener of claim 1, wherein said continuous helical coil has a pitch between coils that can be varied by an applicator.

6. The fastener of claim 1, wherein said continuous helical coil has a pitch sufficient to entrap tissue between coils.

7. The fastener of claim 1, wherein said continuous helical coil has a pitch that can be increased as said fastener is inserted into the tissue.

8. The fastener of claim 1, wherein said continuous helical coil has a pitch of .050 inches.

9. The fastener of claim 1, wherein said continuous helical coil has a pitch range from 0 to a maximum of 3.0 times a diameter of said helical coil.

10. The fastener of claim 1, wherein said means for inserting said continuous helical coil is a T-bar at said proximal end.

11. The fastener of claim 10, wherein a rotational force and a longitudinal force is applied to said T-bar by an applicator that rotates and delivers said continuous helical coil into tissue.

12. The fastener of claim 1, wherein said continuous helical coil is sized to fit within a cannula having a diameter of at least 1mm.

13. The fastener of claim 1, wherein at least a portion of said continuous helical coil is coated with a biocompatible lubricious material for facilitating delivery of the fastener into tissue.

14. The fastener of claim 1, wherein said continuous helical coil is made from absorbable material.

15. The fastener of claim 1, wherein said continuous helical coil is made from a metallic material selected from the group of materials consisting essentially of titanium, titanium alloys, stainless steel and nickel chrome alloys.

5

16. The fastener of claim 1, wherein said continuous helical coil is made from a polymeric material selected from the group of materials consisting essentially of plastics, liquid crystal

10 polymers, HDPE, polyglycolic acid, and polyglycolid hydroxgacetic acid.

17. The fastener of claim 1, wherein said continuous helical coil is longitudinally collapsible and expandable.

18. The fastener of claim 1, further comprising one or more barbs projecting in reverse direction and positioned proximate to said tissue piercing means.

19. A fastener for ligating tissue or for attaching an implantable device, the fastener comprising:

a continuous helical coil having a distal end and a proximal end;

5 a point on said distal end for piercing the tissue;

a first helical coil section adjacent said distal end and having a gap between said point and said first helical coil section; and

10 a T-bar section at said proximal end for engagement with an applicator for inserting said helical coil through the tissue to position and attach the implantable device.

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20. The fastener of claim 19, wherein said gap is adapted to determine depth of penetration and pitch of the fastener in tissue and retentive strength of the fastener to tissue.

21. The fastener of claim 19, wherein said continuous helical coil has a uniform pitch between coils.

22. The fastener of claim 19, wherein said continuous helical coil has a pitch between coils that can be varied by the applicator.

23. The fastener of claim 19, wherein said continuous helical coil has a pitch that can be increased as the fastener is inserted into the tissue.

24. The fastener of claim 19, wherein said continuous helical coil is made from absorbable material.

25. The fastener of claim 19, wherein said continuous helical coil is made from a metallic material selected from the group of materials consisting essentially of titanium, titanium alloys, stainless steel and nickel chrome alloys.

26. The fastener of claim 19, wherein said continuous helical coil is made from a polymeric material selected from the group of materials consisting essentially of plastics, liquid crystal polymers, HDPE, polyglycolic acid and polyglycolid
5 hydroxgacetic acid.

27. The fastener of claim 19, wherein said continuous helical coil is longitudinally collapsible and expandable.

28. The fastener of claim 19, further comprising one or more barbs projecting in reverse direction and positioned proximate to said point.

29. A fastener for ligating tissue or for attaching an implantable device, the fastener comprising:

a continuous double helical coil having a
5 distal end and a proximal end;
said distal end terminating with dual points each for piercing the tissue;
dual first helical coil sections adjacent said distal end each being associated with one of said
10 dual points and each defining a gap therebetween; and
a connecting bar at said proximal end for engagement with an applicator for inserting said double

helical coil through the tissue to position and attach the implantable device.

30. The fastener of claim 29, wherein said gap is adapted to determine depth of penetration and pitch of the fastener in tissue and retentive strength of the fastener to tissue.

31. The fastener of claim 29, wherein said continuous double helical coil has uniform pitch between coils.

32. The fastener of claim 29, wherein said continuous double helical coil has a pitch between coils that can be varied by the applicator.

33. The fastener of claim 29 wherein said continuous double helical has a pitch that can be increased as the fastener is inserted into the tissue.

34. The fastener of claim 29, where said continuous double helical coil is made from absorbable material.

35. The fastener of claim 29, wherein said continuous double helical coil is made from a metallic material selected from the group of materials

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consisting essentially of titanium, titanium alloys,
5 stainless steel and nickel chrome alloys.

36. The fastener of claim 29, wherein said
continuous double helical coil is made from a polymeric
material selected from the group of materials
consisting essentially of plastics, liquid crystal
5 polymers, HDPE, polyglycolic acid and polyglycolid
hydroxycacetic acid.

37. The fastener of claim 29, wherein said
continuous double helical coil is longitudinally
collapsible and expandable.

38. The fastener of claim 29, further
comprising a pivot post extending from said connecting
bar and toward said distal end, said pivot post having
a pointed terminal end.

39. The fastener of claim 29, further
comprising one or more barbs projecting in reverse
direction and positioned proximate to said dual points.

40. An applicator for attaching fasteners to
body tissue comprising:

a distal portion having an elongate outer
tube, a connecting end and a terminal end;

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a proximal portion having a handle and an
5 actuator, said proximal portion attached to said
connecting end of said distal portion;
a rotator contained in said outer tube;
said rotator adapted to receive a plurality
of fasteners and adapted to cooperate with said
10 actuator; and
means for threading and ejecting the
fasteners out of said terminal end.

41. The applicator of claim 40, further
comprising:

a lock/clip indicator adapted to engage said
plurality of fasteners; and
5 a load spring adapted to apply longitudinal
forces against said lock/clip indicator and to bias
said plurality of fasteners toward said terminal end.

42. The applicator of claim 41, wherein said
lock/clip indicator is configured to prevent actuation
of said actuator upon discharge of said plurality of
fasteners from the applicator.

43. The applicator of claim 40, wherein a
groove extends longitudinally along substantially the
length of said rotator, said groove adapted to receive
coils of said plurality of fasteners.

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44. The applicator of claim 40, wherein said rotator has a cross-sectional profile approximating a D-shape and is adapted to receive coils of said plurality of fasteners.

45. The applicator of claim 40, wherein said threading and ejecting means is a thread form contained in an interior of said terminal end adapted to engage said plurality of fasteners.

46. The applicator of claim 45, wherein said thread form is an interlock spring fixedly retained in said interior of said terminal end.

47. The applicator of claim 40, wherein said threading and ejecting means a nose piece attached to said terminal end, said nose piece having structure projecting perpendicularly toward a longitudinal axis
5 of said outer tube and adapted to engage said plurality of fasteners.

48. The applicator of claim 40, wherein said distal portion and said proximal position are releasably secured together.

49. The applicator of claim 48, wherein said distal portion is disposable and said proximal portion is reusable.

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50. The applicator of claim 40, wherein said actuator includes:

a lever having a first end and a second end, said lever pivotally attached about a midpoint to said handle;

said first end of said lever adapted to be
5 gripped by hand;

a lead screw rotatably attached to an interior of said handle;

a nut driver, said second end of said lever pivotally attached to said nut driver, said nut driver
10 adapted to travel along said lead screw, thereby turning said lead screw; and

said lead screw attached to said rotator so that as the lever is depressed by hand the nut driver will travel along the lead screw toward said rotator
15 thereby turning said rotator in the process.

51. The applicator of claim 50, wherein said lead screw is a high helix lead screw.

52. The applicator of claim 50, wherein said lever has a midsection extension.

53. The applicator of claim 52, further comprising gear teeth formed within said interior of said handle.

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54. The applicator of claim 53, further comprising a spring loaded pawl pivotally attached to said midsection extension and adapted to engage said gear teeth.

55. The applicator of claim 40, wherein said actuator includes:

a lever having a first end, a midsection, and a second end, said first end pivotally attached to said
5 handle, said midsection adapted to be gripped by hand;

a lead screw rotatably attached to an interior of said handle;

a nut driver, said second end pivotally attached to said nut driver, said nut driver adapted to
10 travel along said lead screw, thereby turning said lead screw; and

means for said lead screw to releasably engage said rotator so that as the lever is depressed by hand, the nut driver will travel along the lead
15 screw toward said rotator thereby turning said rotator in the process and so that when the lever is returned to its undepressed position, the lead screw will rotate in the reverse direction and independently of the rotator which remains stationary.

56. The applicator of claim 55, wherein said lead screw is a high helix lead screw.

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57. The applicator of claim 55, wherein said releasable engagement means is a ratchet mechanism.

58. The applicator of claim 55, wherein said lever has a mid-section extension, formed in said mid-section extension are a plurality of teeth.

59. The application of claim 58, further comprising a latch pawl cooperating with said teeth to prohibit said lever from backstroking until it has been completely depressed.

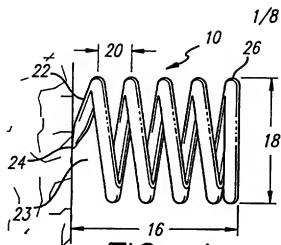


FIG. 1

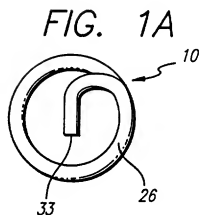


FIG. 1A

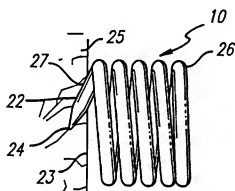


FIG. 1B

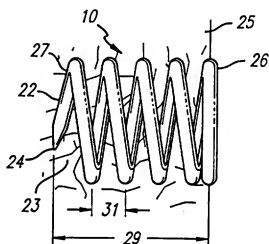


FIG. 1C

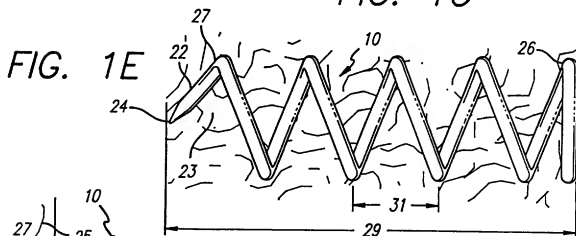


FIG. 1E

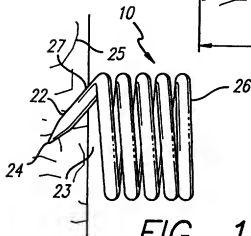


FIG. 1D

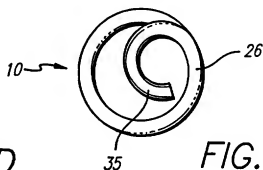


FIG. 1F

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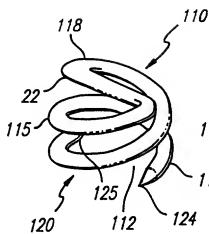


FIG. 2

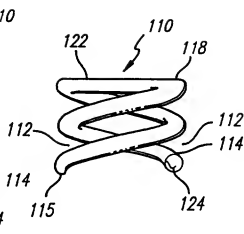


FIG. 2A

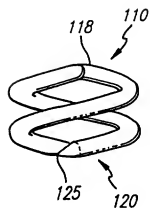


FIG. 2B

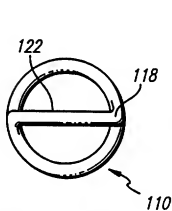


FIG. 2C

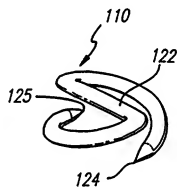


FIG. 3

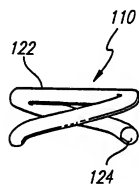


FIG. 3A

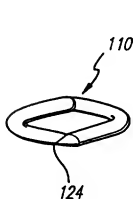


FIG. 3B

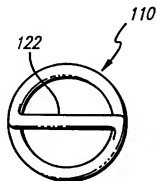


FIG. 3C



FIG. 4

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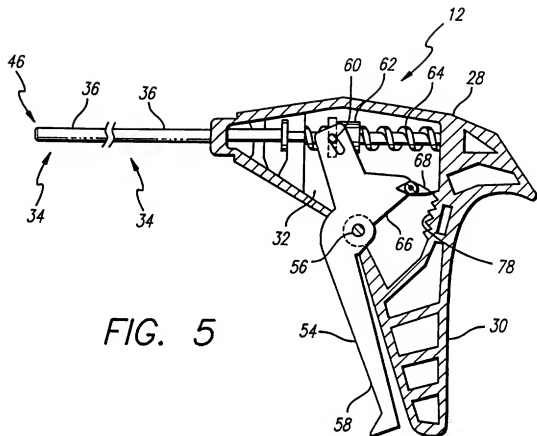


FIG. 5

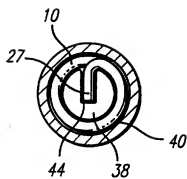


FIG. 6A

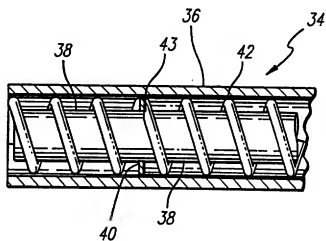


FIG. 6

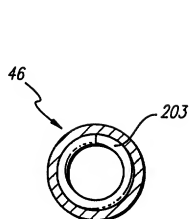


FIG. 7A

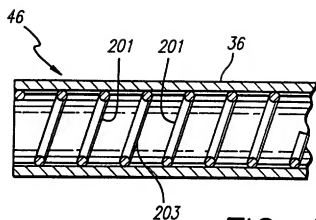


FIG. 7

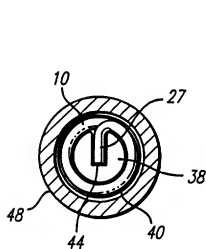


FIG. 8A

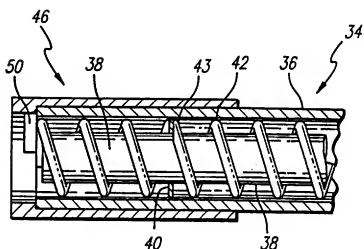


FIG. 8

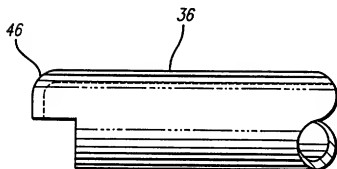


FIG. 9

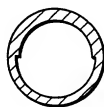


FIG. 9A

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FIG. 10

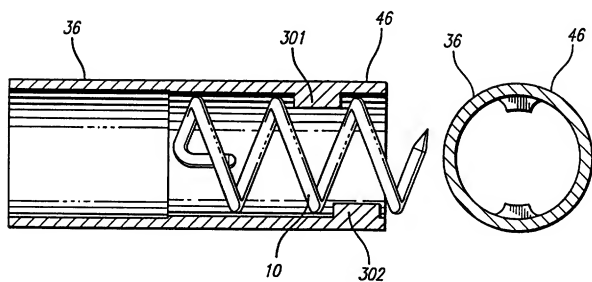
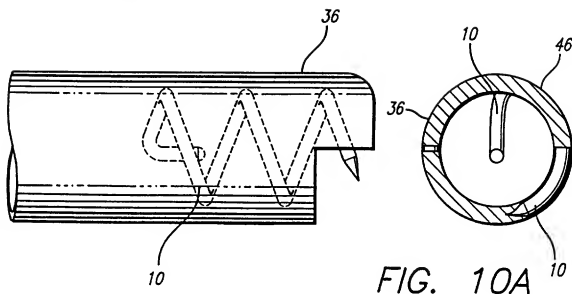


FIG. 11

FIG. 11A

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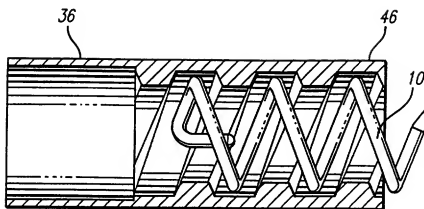


FIG. 12

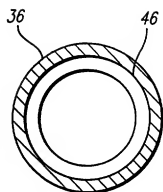


FIG. 12A

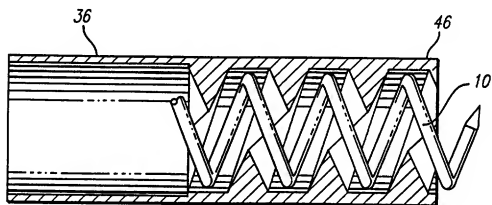


FIG. 13

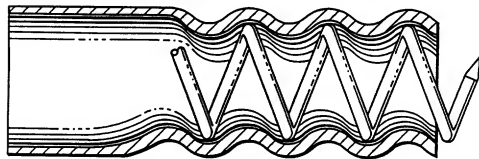


FIG. 14

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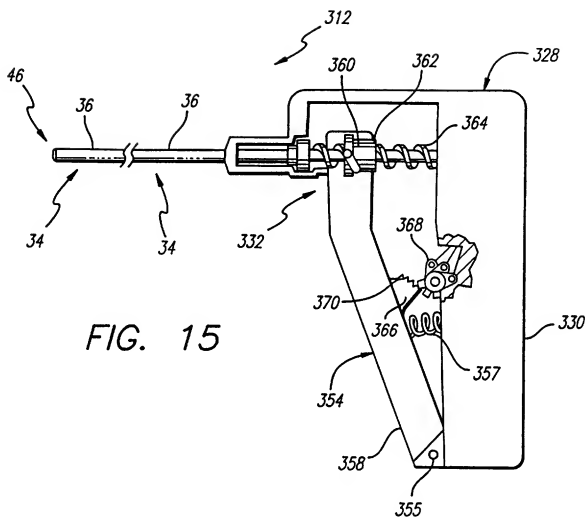


FIG. 15

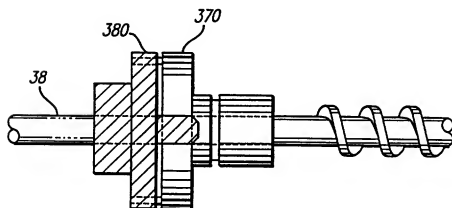


FIG. 16

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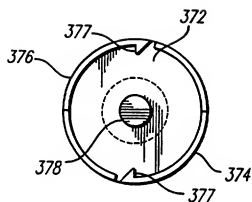


FIG. 16A

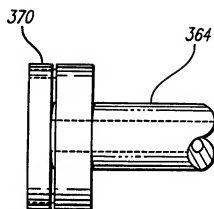


FIG. 16B

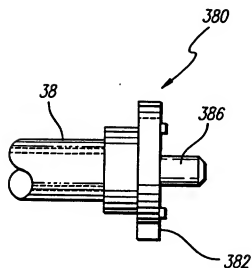


FIG. 16C

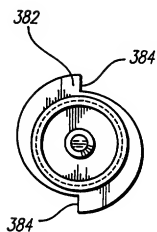


FIG. 16D

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61B17/06 A61B17/04

According to International Patent Classification (IPC) or to both national classification and IPC

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Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP,A,0 121 362 (ETHICON INC.) 10 October 1984 see page 2, line 29 - page 3, line 28 see page 4, line 26 - page 5, line 11 see page 7, line 8-34; claims 1-8; figures 1-3	1-9,12, 15,17
A	---	19,29
X	WO,A,90 14795 (YOON) 13 December 1990 see abstract; figures 10-14 see page 20, line 3 - page 24, line 18	1-14, 16-28
A	---	29
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Date of the actual completion of the international search

24 November 1995

Date of mailing of the international search report

04.12.95

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Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR,A,2 377 796 (V. N.-I. I. I. M. T.) 18 August 1978	1-9, 12-14, 16,17
A	see the whole document	19,40

X	DE,C,295 962 (KUHLEMANN) 6 May 1916	1-4,6, 8-11,15, 19-21,25
	see page 1, right column, line 51-54; claim; figures	

A	US,A,3 858 783 (KAPITANOV ET AL.) 7 January 1975	40

A	FR,A,320 731 (BROWN) 18 December 1902 see figures 1-6	29

A	US,A,5 007 921 (BROWN) 16 April 1991 see figures	29

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internat. Application No

PCT/US 95/07270

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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DE-C-295962		NONE	
US-A-3858783	07-01-75	NONE	
FR-A-320731		NONE	
US-A-5007921	16-04-91	US-A- 5026390	25-06-91



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 17/115, A61F 2/06, A61B 17/064		A1	(11) International Publication Number: WO 97/03616
			(43) International Publication Date: 6 February 1997 (06.02.97)
(21) International Application Number: PCT/GR96/00017 (22) International Filing Date: 5 July 1996 (05.07.96) (30) Priority Data: 950100267 14 July 1995 (14.07.95) GR (71)(72) Applicants and Inventors: SKARDOUTSOS, Spiros [GR/GR]; 16 K. Kotta, N. Psychico, GR-155 25 Athens (GR). CONSTANTINO, Marios [GR/GR]; 9 Thrakis, Kifissia, GR-145 61 Athens (GR).		(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>	
(54) Title: ANGIOSURGICAL DEVICE AND VASCULAR GRAFT AND VASCULAR ANNULUS FOR VESSEL-VASCULAR GRAFT BINDING			
(57) Abstract This invention aims at the trapping of the vessel free cut end by plug-button connectors and its binding with the vascular graft. According to the invention a stapler whose mandibles are perimetrcally closed towards a shaft of the device which has the vascular graft, is equipped with plug-button connectors and can place them stapling the vessel-vascular graft. It can also only have part of the ligaments (plug or button) and the corresponding one can be integrated at the vascular graft or may have the graft which forms free double ends at its edge and all their mechanisms are integrated. Alternatively, the vascular graft with the free double ends can be bound to the vessel without the help of the device. Finally, and intermediate binding annulus can be employed between vessel-vascular graft, which is bound to the vessel by plug-button connectors in the same way as the graft.			

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**ANGIOSURGICAL DEVICE AND VASCULAR GRAFT AND VASCULAR ANNULUS
FOR VESSEL-VASCULAR GRAFT BINDING**

5 This invention refers to the safe and blood-proof connection of
a vessel with a vascular graft either by an automatic device or by
hand.

The anastomosis of a vessel to a vascular graft is problematic
by nature due to the pathological and brittle state of the vessel wall in
cases where part of the vessel must be replaced by a vascular graft
10 e.g. aortic aneurysm and due to the presence of hydraulic pressures
and pulse leading to sporadic ruptures of the wall by the stapler clip
itself e.g. stitch employed for the anastomosis.

The anastomosis of vessel - vascular graft must be blood-
proof otherwise the patient's life is in great danger.

15 The application of such an anastomosis requires the
interruption of the blood flow through the vessel which is
accomplished by the placement of a vascular clamp. The duration of
the interruption of the blood flow is a major factor for the outcome of
the operation and must be the least possible one considering the
20 numerous side effects which it causes to the organism.

The currently, extensively applied suturing means exerts great
pressure against the vessel wall at the binding point due to its small
diameter, resulting in ruptures of this wall, to a smaller or larger
extent, frequently leading to uncontrolled haemorrhage.

25 The present invention aims at the safe and blood-proof vessel-
vascular graft binding eliminating increased tensions from the stapler
clip to the vessel wall and consequently at the preservation of its
integrity as well as the execution of this binding in less time. The

above mentioned are accomplished by the use of plug-button ligaments. The invention reveals the alternative ways of their use either by an automatic stapler equipped with such ligaments or by a vascular graft where the plug or the button or both parts of the ligaments are integrated or finally by the application of an annulus first to the vessel by plug-buttons ligaments and then to the vascular graft by a simple mechanic binding.

The short description of the following figures refers to the realisation of the invention given as an example without the intention of limiting it.

Figure 1: Is the representation of the angiosurgical device.

Figure 2: Is the representation of the attachment of the device, the shaft.

Figure 3: Is the representation of the shaft coated by a vascular graft.

Figure 4: Is the representation of a plug-button connector.

Figure 5: Is the representation of the angiosurgical device equipped with plug-button connectors.

Figure 6: Is the representation in cross-section of the angiosurgical device bringing the vascular graft to the suturing point.

Figure 7: Is the representation of a vascular graft with free double ends at the edge.

Figure 8: Is the representation of a vascular graft with free double ends and integrated plug - button connectors.

Figure 9: Is the representation of the suturing of a vessel-vascular graft by plug-button connectors.

During the referred suturing procedure, the vessel wall is maintained in contact with the wall of the vascular graft by

compression among the bases of a much larger surface than the transverse surface of the axis which penetrates the vessel wall.

The attachment is accomplished as the axis of the connector penetrates the vessel and possibly the graft - unless the connectors
5 are integrated in the graft as it is safely "locked" at the button receptor.

The small differences in thickness of the vessel wall are covered either by the fact that, occasionally, the axis enters the button receptor at different depths or in the case of the integrated
10 button in the vascular graft by the fact that the axis can enter the thickness of the graft wall.

The placement and connection of the graft or the ring to the vessel can be employed either by the use of the described device or by hand as long as the connectors are integrated in them, either by
15 clamp placed by each of the plug - button connectors.

Referring to the invention in detail in figure (1) we can see an angiosurgical device which has an attachment at the shaft (11) and mobile mandibles which enclose the shaft and converge towards it during the suturing. The sutured elements are placed in between
20 shaft-mandibles and pressed between the largest perimeter of the shaft and the corresponding points of the inner surface of the mandibles next to their edges (23).

The shaft is bound to the main body of the device with a receptor (13), from which it can be detached, while the mandibles are
25 bound to the main body by the articulations (22).

Figure 2 shows a shaft which has a smooth free edge and its larger perimeter is next to this edge. The free edge of rounded or oval cross-section enters the vessel lumen as far as the largest

perimeter.

Figure 3 shows a shaft coated by a vascular graft whose edge exactly covers the largest perimeter of the shaft (12). The vascular graft enters the vessel lumen together with the edge of the shaft. The vessel and vascular graft are compressed in between the shaft and mandibles when the device is used.

Figure 4 shows a plug-button connector. The thin axis (42) penetrates the vessel wall and enters the button receptor (44) where it locks. The vessel wall is trapped among the wide bases of the plugs (41) and the buttons (43).

Figure 5 shows the angiosurgical device equipped with plug-button connectors. The buttons (43), are at the largest perimeter of the shaft, in receptors, and the plugs (41) are at the corresponding points of the mandibles (23) in such a way so that during the convergence of the mandibles towards the shaft and the pressure on it each plug is bound with the corresponding button.

Figure 6 shows the shaft (11), in cross-section at the suturing level, which has buttons (43) coated by graft (71) and around it the mandibles (21) which have the plugs (41). The buttons are uniformly distributed in the perimeter of the shaft.

Figure 7 shows a vascular graft (71) which by adhesion, has parts made of its own material or of another bio-compatible material (72) which surround this edge of the graft and form free double ends.

Figure 6 shows a vascular graft (71) with free double ends at its edge, which has integrated plug-button ligaments, the buttons (43) are at the edge of the outer surface of the graft tube, the plugs (41) are at the end of the inner part of the adhesive parts (72). The binding with the vessel is executed by trapping the edge of the

vessel between the cut ends of the graft connected to the plug-buttons connectors.

Figure 9 shows the binding of a vessel to a vascular graft executed by the binding of each plug with the corresponding button.

5 Figure 10 shows a vascular annulus (81) consisting of an integral tube that forms at its one edge free double ends, its inner cut end is formed by the edge of the tube (84) and the outer by the part or the parts which can converge and cover the outer surface of the inner cut end.

10 At the edge of the outer surface of the inner cut end (84) are the buttons of the plug-button connectors and at the corresponding points of the inner surface of the outer cut end (83) are the plugs, in such a way that with the convergence of the two cut ends, the plug is bound to the corresponding button trapping the intermediately placed
15 edge of the vessel.

The other edge of the annulus (82) has a receptor for simple mechanic binding to the edge of the graft which has the corresponding receptor.

20 Figure 11 shows a vascular annulus (81) integrated at the edge of the vascular graft (71) in a way that the vascular graft coats the whole inner surface of the ring. The annulus forms free double ends (41, 43) as described in figure 9, in a way that the trapping of the vessel (60) between the cut ends of the annulus can create integral continuity of the vessel-vascular graft contact.

CLAIMS

1. The angiosurgical device is characterised by the fact that it is used for the binding of a vessel - vascular graft. This device has an oblong attachment, of unequal thickness, the shaft (11) is connected
5 to the main body of the device and it can be covered by a vascular graft or a vascular ring. The device has mobile mandibles (21) joined to the main body of the device by articulations (22). The mandibles are perimetrically placed around the shaft, in a distance from the shaft, before the suturing. The device has a mechanism for the
10 convergence of the mandibles and their approach towards the shaft during the suturing.
2. The angiosurgical device according to the first claim above, is characterised by the fact that the upper shaft (11) is connected, by one edge (13), to the main body of the device from which it can be
15 detached by exerting controlled pressure on the shaft and can be placed on it again.
3. The angiosurgical device according to the 1st & 2nd claims above, is characterised by the fact that the free end of the shaft is made smooth, with a rounded or oval cross-section and next to this
20 edge the largest perimeter of the shaft (12) is formed, where the edge of the graft or the annulus is placed. This perimeter, together with the edge of the graft or the annulus, enters the vessel lumen during the suturing procedure.
4. The angiosurgical device according to the above claim, is
25 characterised by the fact that the shaft has receptors at the point of its largest perimeter (12). The buttons or the plugs of the plug-button connectors are placed perimetrically to these receptors.
5. The angiosurgical device according to the 1st claim above, is

characterised by the fact that the mobile mandibles (21) form a curved surface with the concave part towards the shaft, and is also characterised by the fact that the points of the inner side of the mandibles next to their free edge (23) correspond to the points of the largest perimeter of the shaft towards which they converge and form the perimeter (12) during suturing.

6. The angiosurgical device according to the 5th claim above, is characterised by the fact that receptors exist, next to the free edges of the mandibles (23) and at their inner side. The plugs or buttons of the connectors that correspond to the ones on the shaft are attached on these receptors.

7. The angiosurgical device according to the above claim, is characterised by the fact that during the suturing, the sutured elements, that is, the edge of the vessel and the edge of the graft are pressed together in between the corresponding points of the shaft (12) and the mandibles (23).

8. This angiosurgical device according to the 7th claim above, is characterised by the fact that during the compression of the sutured elements between shaft-mandibles, each plug is bound to the corresponding button making the vessel - vascular binding permanent (figure 9).

9. The vascular graft according to the 1st claim is characterised by the fact that next to one of its edges it has an attached part as of the graft or of another bio-compatible material (72). The parts encircle the corresponding part of the graft in a way that when these parts converge at the graft, their edges form the perimeter of the edge of the graft so that free double ends are formed at the edge, i.e. the inner cut edge from the integral tube of the vessel and the outer

cut edge from the attached parts. The free edge of the vessel is trapped in between the two cut ends during the suturing.

10. The vascular graft according to the 9th claim is characterised by the fact that the integrated buttons or plugs of the plug-button connectors are on the inner surface of the outer cut end of the edge of the graft. And, the corresponding buttons or plugs are on the outer surface of the inner cut end, at corresponding points. During the suturing, each plug is bound to the corresponding button, permanently trapping the edge of the vessel between the two cut ends of the graft.

11. The vascular graft according to the 10th claim, is characterised by the fact that it is on the angiosurgical device as described in the 1st requirement above. The main tube of the graft (72) is in contact with the inner surface of the mandibles (21) from which during the suturing they are pushed and pressed in a way that each plug is bound to the corresponding button, permanently trapping the edge of the vessel which was placed in-between the shaft and mandibles.

12. The vascular annulus according to 1st claim above, is characterised by the fact that it can be the intermediate ligament between the vessel and vascular graft. This vascular annulus consists of bio-compatible elastic material and forms at its one edge free double ends, the inner cut end constitutes part of an integral tube (84) and has the buttons or the plugs of the plug-button ligaments at the edge of its outer surface. The outer cut end (83) has at the edge of its inner surface the corresponding plugs or buttons at corresponding points in a way that during the convergence of the two cut ends, each plug is bound to the corresponding button trapping the edge of the vessel which has been placed in-between.

13. The vascular annulus according to the 12th claim above, is characterised by the fact that the edge which does not form free double ends has a receptor for simple mechanic binding to the edge of the graft (82).

5 14. The vascular annulus according to the 12th claim above, is characterised by the fact that is integrated at the edge of the vascular graft (Fig. 11) in a way that this edge of the graft covers the inner surface of the tube formed by the vascular annulus.

10 15. The vascular annulus according to the 12th claim, is characterised by the fact that has an angiosurgical device as described by the 1st claim covering part of the shaft as far as its largest perimeter. The outer cut end is pressed by the mandibles to bind itself to the inner cut end of the annulus with the plug-button connectors, trapping the free cut end of the vessel which has been
15 placed in between.

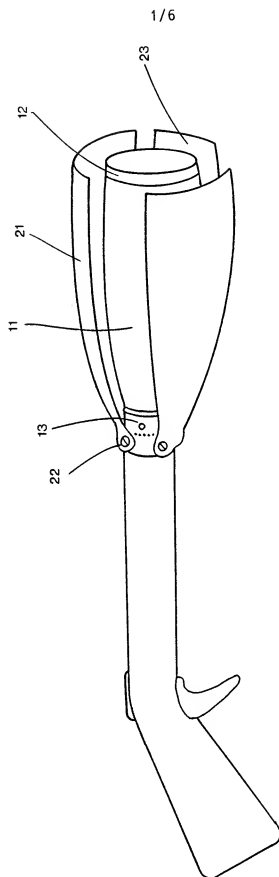


Fig. 1

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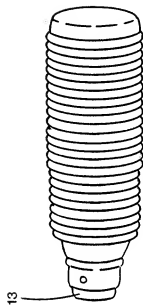


Fig. 3

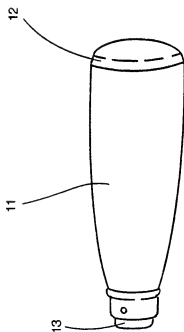


Fig. 2

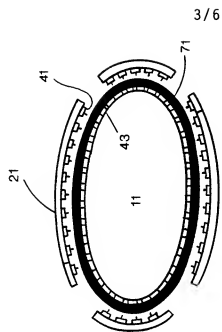


Fig. 6

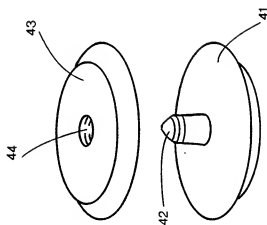


Fig. 4

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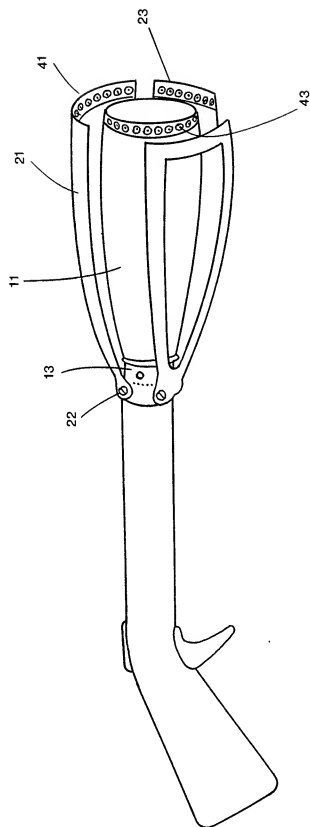


Fig. 5

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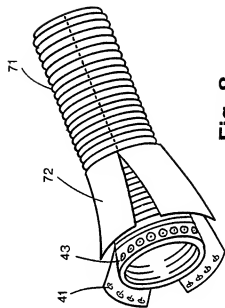


Fig. 8

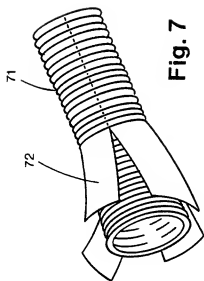


Fig. 7

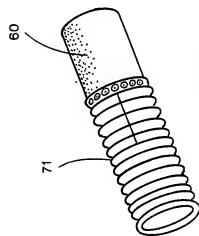


Fig. 9

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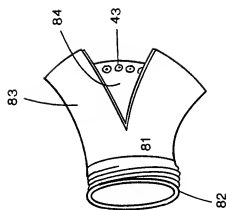


Fig. 10

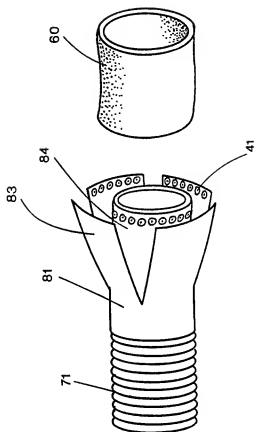


Fig. 11

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/GR 96/00017

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61B17/115 A61F2/06 A61B17/064

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A,5 151 105 (KWAN-GETT CLIFFORD) 29 September 1992 see column 8, line 9 - line 47 ---	1
A	US,A,4 352 358 (ANGELCHIK JEAN P) 5 October 1982 see column 4, line 15 - line 22 ---	9,12
A	WO,A,93 00868 (OWEN EARL RONALD) 21 January 1993 see page 1, line 27 - page 2, line 18 -----	9



Further documents are listed in the continuation of box C.



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Date of the actual completion of the international search

3 October 1996

Date of mailing of the international search report

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Gérard, B

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GR 96/00017

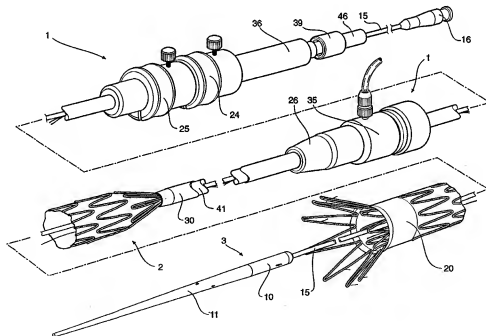
Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-5151105	29-09-92	NONE	
US-A-4352358	05-10-82	NONE	
WO-A-9300868	21-01-93	AU-B- 658915	04-05-95
		CA-A- 2112474	21-01-93
		EP-A- 0593600	27-04-94
		JP-T- 7500023	05-01-95
		US-A- 5456714	10-10-95



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/AU98/00383</p> <p>(22) International Filing Date: 25 May 1998 (25.05.98)</p> <p>(30) Priority Data: PO 7008 26 May 1997 (26.05.97) AU</p> <p>(71) Applicant (for all designated States except US): WILLIAM A. COOK AUSTRALIA PTY. LTD. [AU/AU]; 12 Electronics Street, Brisbane Technology Park, Eight Mile Plains, QLD 4113 (AU).</p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only): HARTLEY, David [AU/AU]; 2 View Street, Subiaco, W.A. 6008 (AU). LAWRENCE-BROWN, Michael [AU/AU]; 36 Shann Street, Floreat, W.A. 6014 (AU).</p> <p>(74) Agent: COLLISON & CO.; 117 King William Street, Adelaide, S.A. 5000 (AU).</p>		<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published With international search report.</p>

(54) Title: A PROSTHESIS AND A METHOD AND MEANS OF DEPLOYING A PROSTHESIS



(57) Abstract

An introducer (1) adapted for the introduction of a self-expanding endovascular prosthesis (20) in a lumen of a patient. The introducer has attachment devices (10, 30) to hold each end of the prosthesis so that each can be moved independently. An endovascular prosthesis (20) is also claimed with stents at the proximal and distal ends being within the graft. The remainder of the stents are positioned on the outside of the graft body.

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TITLE: A PROSTHESIS AND A METHOD AND MEANS OF
DEPLOYING A PROSTHESIS

5

FIELD OF INVENTION

This invention relates to a method and means for introducing a expandable intraluminal prosthesis which may be straight, tubular or bifurcated in form and intended for the endovascular repair of diseased or damaged vessels and to a prosthesis which is suitable for such a procedure.

10

Throughout this specification the terms proximal and proximally are used for a position or direction towards the patient's heart and the terms distal and distally are used for a position or direction away the patient's heart.

BACKGROUND OF THE INVENTION

15 The deployment of intraluminal prostheses into the lumen of a patient from a remote location by the use of a deployment device or introducer has been disclosed in a number of earlier patent specifications.

United States Patent No. 4,562,596 in the name of Kornberg proposes the retention of a self expanding graft within a sleeve until it is to be deployed at which time the sleeve is withdrawn and the graft allowed to expand. After the graft has been released there is no possible control of the position of the distal end of the graft. Inadequate placement can render the entire deployment null and void.

20

United States Patent No. 4,665,918 in the name of Garza et al proposes a system and method for the deployment of a prosthesis in a blood vessel. The prosthesis is positioned between a delivery catheter and an outer sheath and expands outwardly upon removal of the sheath. Once again after the prosthesis has been released by removal of the sheath there is no possible control of the position of the either end of the prosthesis.

25

30 United States Patent No. 4,950,227 in the name of Savia et al proposes the delivery of a stent by mounting the stent to the outside of an inflatable catheter and retaining the ends of an unexpanded stent by fitting sleeve over

- either end of the stent. Expansion of the stent is caused by inflation of the catheter between the sleeves so that the ends of the stent are withdrawn from the respective sleeves and the stent released and expanded into position. This system provides very little control over the deployment procedure and in practice would be impractical for intraluminal deployment where accuracy is vital.
- 5

- European Patent specification No. 472 731 In the name of Inoue proposes an artificial tube prosthesis to be inserted into a human organ in a folded condition retained within a catheter and released to expand within the organ.
- 10 Deployment is achieved by retention of the proximal end of the prosthesis by wires passing through a tube through the middle of the prosthesis while withdrawing the catheter. A balloon is then used to expand the prosthesis. Once again after the prosthesis has been released by removal of the catheter there is no possible control of the position of the distal end of the prosthesis.
- 15 United States Patent No. 5,071,407 in the name of Termin et al proposes the delivery of a stent by retaining the stent in an elastically deformed condition between a catheter and a sheath. The proximal end of the stent is retained at the catheter. The stent is allowed to expand by removal of the sheath and optional balloon expansion. No indication is given of any method for release
- 20 of the stent from the catheter or how the distal end of the stent can be positioned accurately.

- Australian Patent Application No. 669,338 in the name of Chuter proposes a delivery arrangement for transluminally positioning a prosthesis at a particular position on an internal wall of a lumen. The delivery arrangement
- 25 has an outer sheath to surround the prosthesis and a retention arrangement to hold the prosthesis in a selected position during removal of the sheath before final release.

- Australian Patent Application No. 671,910 in the name of Endovascular Technologies, Inc. proposes a delivery arrangement for positioning a
- 30 prosthesis within a lumen. It has capsules which retain each end of the prosthesis and a balloon arrangement to expand the prosthesis when the capsules have been retracted to release the prosthesis. A sheath is used to protect the prosthesis during insertion. Once the capsules have been withdrawn there is no method provided to ensure that the ends of the

prosthesis are correctly positioned.

It is the object of this invention to provide a graft and a method and apparatus to deploy the graft prosthesis which will overcome at least some of the problems discussed above or at least provide an alternative arrangement to the prior art systems described above.

BRIEF DESCRIPTION OF THE INVENTION

According to one aspect of the present invention there is provided an introducer for positioning an expandable endovascular prosthesis. In a lumen of a patient, the prosthesis having a proximal portion and a distal portion, the introducer comprising a prosthesis positioning mechanism selectively releasable from the prosthesis when the prosthesis is positioned at a desired site in the lumen of a patient, a first control member controlling at least the longitudinal position of the proximal portion of the prosthesis; and a second control member controlling at least the longitudinal position of the distal portion of the prosthesis. The prosthesis positioning mechanism can include a distal attachment region and/or a proximal attachment region. The distal attachment region can include a distal attachment device. The proximal attachment region can include a proximal attachment device. The prosthesis positioning mechanism can preferably include a control arrangement for controlling the length of the prosthesis. The prosthesis positioning mechanism can also preferably include a rotational arrangement by which the relative angular orientation of the proximal and distal portions of the prosthesis can be adjusted. This prosthesis positioning mechanism can singly or in combination also adjust the angular orientation of the prosthesis. The introducer can also preferably comprise an expansion control mechanism for controlling expansion of the prosthesis when the prosthesis is positioned at the desired site in the lumen of the patient.

According to another aspect of the present invention therein provides an endovascular arrangement for positioning an expandable prosthesis at a desired location in a lumen of a patient, said arrangement comprising a control section to be maintained external to the patient, and a prosthesis positioning mechanism controllable by the control section for moving and manipulating the prosthesis to a desired location in the lumen, wherein a first member extends from the control section to a proximal region of the

positioning mechanism, the proximal region of the positioning mechanism having means for controlling the proximal end of the prosthesis, wherein a second member extends from the control section to a distal region of the positioning mechanism, the distal region having means for controlling the distal end of the prosthesis in cooperation with the second member. The arrangement further preferably comprises contraction means for containing self-expanding stents of the prosthesis during insertion of the prosthesis positioning mechanism into the lumen and/or expansion means for expanding expandable stents of the prosthesis when the prosthesis is positioned at the desired site in the lumen of the patient. The contraction means preferably includes tubular means that extends from the control section to the positioning mechanism and serves to contain the prosthesis during insertion of the positioning mechanism into the lumen and to control the distal end of the prosthesis when the tubular means has been moved in a distal direction relative to the first and second members, relative movement between the first and second members enabling manipulation of the prosthesis when in the lumen. The expansion means includes at least radial means such as preferably an inflatable balloon for radially expandable stents of the prosthesis when the prosthesis is positioned at the desired location in the lumen. The first and second members can be contained within the said tubular means. Means can be provided for clamping the first and second members together during insertion of the prosthesis and for releasing the first and second members prior to the manipulation. Expansion of a non self expanding prosthesis can be performed by expansion of a balloon located around the first member and within the prosthesis, said balloon being inflatable from the control section. The proximal region of the attachment mechanism can contain tubular means for containing the proximal end of the prosthesis prior to final positioning thereof, and release of the prosthesis from the tubular means can be achieved by proximal movement of the first member. The second member has means for controlling the distal end of the stent whilst the latter is inside tubular means. The arrangement can further comprise release mechanisms in the control section for controlling wires extending to respective stents of the prosthesis, The prosthesis positioning mechanism can preferably include a control arrangement for controlling the length of the prosthesis, The prosthesis positioning mechanism can also preferably include a rotational arrangement by which the relative angular orientation of the proximal and distal portions of the prosthesis can be adjusted. This prosthesis positioning mechanism can singly or in

combination also adjust the angular orientation of the prosthesis. The introducer can also preferably comprise an expansion control mechanism for controlling expansion of the prosthesis when the prosthesis is positioned at the desired site in the lumen of the patient.

- 5 The above introducer and/or arrangement can be used to locate expandable prosthesis or self-expandable prosthesis. If the former are used, then one or more balloons, inflatable from a control section or external the patient, can be used.

- 10 The first member in the endovascular arrangement can either be fixed to an extension or the member can actually be shaped into the form of the extension .

- 15 The first and second control members of the introducer can singly or in combination preferably include a trigger wire positioned at the proximal and/or distal ends of the prosthesis. The trigger wire(s) can preferably extend to one or more release mechanisms external to patient for releasing the prosthesis from the positioning mechanism when the prosthesis is positioned at the lumen site in the patient.

- 20 Some form of container or expansion control mechanism can be used to contain that end while the remainder of the prosthesis is being manipulated in the lumen of the patient It is after the manipulation has been executed that the container is removed by operation of the various control members.

- 25 In another aspect of the invention, the introducer or endovascular arrangement of the invention can also comprise a control arrangement for controlling the length of the prosthesis during the manipulation in the patient. In one aspect, the control arrangement or members can preferably include coaxial tubes which are connected to the respective ends of the prosthesis for rotation thereof When the control members are locked together, the entire prosthesis can be rotated in the lumen of the patient. Alternatively, the control arrangement and/or members can be individually controlled for rotating the relative ends of the prosthesis with respect to each other In the same or
30 opposite directions.

The sleeve can be independently located relative to the control arrangement

and/or the first and second control members. The control arrangement or members can also be contained within the sleeve. The sleeve can preferably be a tube, wraps of wire, or can be a tube with wire therein. The aforementioned trigger or release wires can also be contained in the sleeve tube or in the wall of the tube.

With respect to expandable prosthesis, the expansion means for expanding expandable stents of the prosthesis can preferably include one or more balloons (more preferably three balloons) for advantageously and independently expanding the proximal and distal portions of the prosthesis as well as the mid section thereof.

In an alternate form the invention may be said to reside in an introducer adapted for the introduction of a self expanding endovascular prosthesis into a lumen of a patient, the prosthesis having a proximal end and a distal end, the introducer comprising, a proximal attachment device adapted to be attached to the proximal end of the prosthesis, a distal attachment device adapted to be attached to the distal end of the prosthesis, each of the proximal and distal attachment devices attaching to the prosthesis in such a manner that the prosthesis can be held in tension therebetween and that each end of the prosthesis can be individually moved in proximal and distal directions and be rotated, and proximal releasing means associated with the proximal attachment device and distal releasing means associated with the distal attachment device to enable selective releasing of the proximal and distal ends of the prosthesis.

In a preferred form of the invention the proximal attachment means has a long tapering flexible extension on its proximal end to facilitate insertion of the introducer into a body lumen and its advancement along the lumen.

The proximal attachment device may be mounted on a flexible thin walled tube which extends in a distal direction from the proximal attachment device to an external manipulation section of the introducer which is adapted to remain external of the patient.

The thin wall metal tube may include fluid connection means external of the patient to enable the introduction of a medical reagent therethrough.

The long flexible extension may include a hollow tube therethrough in fluid communication with the thin wall metal tube and a plurality of side holes to enable dispersion of the medical reagent proximal of the prosthesis.

- 5 In a preferred form of the invention the distal attachment device is mounted on a flexible thick walled tubing and coaxial on the thin walled tube and extending in a distal direction to the external manipulation section and mounted such that the respective tubes can be moved together or independently.

- 10 There may be further included a haemostatic seal between the thin walled tube and the thick walled tube in the manipulation section.

There may be further included means to introduce a medical reagent into an annular space defined between the thin walled tube and the thick walled tube.

- 15 In a preferred form of the invention there may be a proximal trigger wire extending from the proximally attachment device to the manipulation section, the proximal trigger wire being adapted to activate the proximal releasing means and a distal trigger wire extending from the distal attachment device to the manipulation section, the distal trigger wire being adapted to activate the distal releasing means.

- 20 In a preferred form of the invention there may be included an external release mechanism for each of the proximal trigger wire and distal trigger wire, the external release mechanism adapted to prevent accidental release of the trigger wires and to allow release of the distal releasing means only after release of the proximal releasing means.

- 25 Preferably there is a haemostatic seal around the respective trigger wires in the manipulation section.

- 30 The introducer may also include an external sheath extending from external of the patient to cover and compress the prosthesis during insertion of the introducer into a patient and movable longitudinally from outside the patient to expose the prosthesis.

The external sheath may be coaxial with and a sliding fit on the thick walled tube. The external sheath may have a proximal end which is tapered and smoothed to present a low resistance to advancement of the introducer during insertion. The proximal end of the external sheath may also be adapted to have a tight fit on to the proximal attachment device.

5

Preferably the distal attachment device is of a streamlined shape and is adapted to be advanced to the proximal attachment device whereby to allow smooth retrieval through the released prosthesis and into the external sheath for removal from a patient.

- 1 0 The introducer according to this invention may be used with a straight tubular self expanding prosthesis or it may be used where the prosthesis is a bifurcated prosthesis.

The introducer according to this invention may be used where the lumen of the patient is an aorta and the prosthesis is adapted to repair an aortic aneurism.

1 5

In an alternative form the invention is said to reside in a method of placing a prosthesis into an internal lumen by means of an insertion assembly the method including the steps of; inserting the insertion assembly including the prosthesis into the internal lumen, withdrawing a sheath from the insertion assembly to expose the prosthesis, releasing the prosthesis from the insertion assembly, replacing the sheath onto the insertion assembly, and retracting the insertion assembly.

2 0

Preferably the prosthesis has a proximal end and a distal end and the insertion assembly includes a proximal attachment device and a distal attachment device adapted to retain the proximal and distal ends of the prosthesis respectively and the step of releasing the prosthesis includes the steps of releasing the proximal end and then the distal end.

2 5

The step of replacing the sheath onto the insertion assembly may include the step of advancing the distal attachment device up to the proximal attachment device and withdrawing the two devices together.

3 0

Between steps (b) and (c) the prosthesis may be manipulated by respective

movements longitudinally and rotationally of the proximal attachment device and distal attachment device to correctly position the prosthesis.

- 5 Where the prosthesis is a bifurcated prosthesis the step of withdrawing the sheath may include the steps of withdrawing the sheath to a first position in which a side arm of the prosthesis is exposed, insertion of an extension prosthesis into the side arm and then full removal of the sheath from the prosthesis.

- 10 Preferably the step of insertion of the extension prosthesis into the side arm comprises the steps of, inserting an extension insertion assembly into the side arm, the extension insertion assembly including a top guide mounted on a catheter, an extension prosthesis on the catheter and a sheath retaining the extension prosthesis and extending over the top guide, withdrawing the sheath to expose and deploy the extension prosthesis, withdrawing the sheath, top guide and catheter together.

- 15 The top guide may include a long proximal nose extension and the catheter may include a distal stop with the extension prosthesis being mounted between the distal stop and the top guide.

- 20 In an alternative form the prosthesis is a bifurcated prosthesis and the step of withdrawing the sheath includes the steps of withdrawing the sheath to a first position in which a first side arm of the prosthesis is exposed, insertion of a first extension prosthesis into the first side arm, then full removal of the sheath from the prosthesis to expose a second side arm and then insertion of a second extension prosthesis into the second side arm.

- 25 The steps of insertion of the first and second extension prosthesis into the first and second side arms comprises the same steps as discussed above.

- 30 In a further form the invention is said to reside in an intraluminal prosthesis having a tubular graft and a plurality of self expanding stents along the length of the graft the prosthesis having a proximal end and a distal end, the prosthesis being characterised by the stents at the proximal end and at the distal end being inside the tubular graft and the remainder of the stents being on the outside of the graft.

10

There may be further included a further self expanding stent mounted to the proximal end of the graft and extending beyond the said proximal end. The further stent may include attachment devices. The attachment devices may comprise barbs extending towards the distal end of the prosthesis.

- 5 The prosthesis may be bifurcated at its distal end to provide a shorter prosthesis leg and a longer prosthesis leg. The shorter leg may have a terminal stent on the outside of the prosthesis and the longer leg have the internal distal stent.

- 10 There may also be an extension prosthesis for insertion into the shorter prosthesis leg, the extension prosthesis comprising a tubular extension prosthesis and a plurality of self expanding stents, the extension prosthesis having a proximal end and a distal end, stents at the proximal and distal ends being inside the tubular extension prosthesis and the remaining stents being on the outside of the prosthesis.

- 15 The intraluminal prosthesis may be constructed so that both the shorter leg and longer leg have external terminal stents and extension prostheses for each leg, each extension prosthesis comprising a tubular extension prosthesis and a plurality of self expanding stents, the extension prosthesis having a proximal end and a distal end, stents at the proximal and distal ends
20 being inside the tubular extension prosthesis and the remaining stents being on the outside of the prosthesis.

Each stent of the intraluminal prostheses according to this invention may be a zig-zag stent.

- 25 Generally it will be seen that by this invention there is provided an arrangement by which a prosthesis can be compressed into a thin insertion device and then the insertion device advanced through a vessel such as a femoral artery until the prosthesis is substantially in the position required and then by careful positioning before release of the attachment means at a proximal end of the prosthesis and then repositioning if necessary before
30 release of the distal end of the prosthesis, the prosthesis can be placed and released accurately.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

1 1

The construction of preferred embodiments and the method by which the device may be operated may be made clearer with the aid of the accompanying drawings which show preferred embodiments of the invention and the method by which the device of the various embodiments may be used. For the purpose of clarity the lumens or vessels into which the prosthesis is to be inserted is not been shown in the drawings except in FIG 18.

In the drawings:

- 1 0 FIG 1 shows a first embodiment of an introducer according to this invention in perspective view with the prosthesis partially deployed,
- FIG 2 shows the first embodiment of the introducer as shown in FIG 1 being fully loaded and ready for introduction into a patient,
- FIG 3 shows the embodiment of FIG 2 in the next stage of deployment of the prosthesis,
- 1 5 FIG 4 shows the embodiment of FIG 2 with the release of the proximal end stage of deployment,
- FIG 5 shows the release of the distal end stage of deployment,
- FIG 6 shows the advancement of the distal attachment device to the proximal attachment device,
- 2 0 FIG 7 shows the withdrawal of the introducer,
- FIG 8 shows that part of the introducer around the distal end of the prosthesis in detail,
- FIG 8A shows an alternative embodiment of that part of the introducer around the distal end of the prosthesis in detail,
- 2 5 FIG 8B shows the embodiment of FIG 8A with the distal attachment device advanced to the proximal attachment device,

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FIG 9 shows that part of the introducer around the proximal end of the prosthesis in detail,

FIG 10 shows that part of the introducer around the haemostatic seal in detail,

5 FIG 11 shows that part of the introducer around the trigger wire release mechanisms in detail,

FIG 12 shows that part of the introducer around the pin vive clamp and the medical reagent introduction tube in detail,

1 0 FIGS 13A - 13C show portions of an alternative embodiment of introducer according to this invention adapted for introduction of a bifurcated prosthesis,

FIG 14 shows an alternative embodiment of introducer according to this invention adapted for introduction of an extension prosthesis,

1 5 FIG 15 shows an embodiment of a bifurcated prosthesis with an extension prosthesis according to this invention,

FIG 16 shows an embodiment of a bifurcated prosthesis with two extension prostheses according to this invention,

FIG 17 shows an embodiment of a prosthesis according to this invention intended for aortouni-iliac deployment, and

2 0 FIG 18 shows a deployed prosthesis according to this invention within an aorta with an aneurism.

Now looking more closely at the drawings and particularly in the embodiment shown in FIGS 1 - 12 it will be seen that an endovascular arrangement such as the introducer according to this invention comprises generally an external manipulation section 1, a distal attachment region 2 and a proximal attachment region 3.

The proximal attachment region 3 shown in detail in FIG 9 includes a

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- cylindrical sleeve 10 with a long tapered flexible extension 11 extending from its proximal end. The extension 11 has an internal longitudinal aperture 12 to enable it to be advanced along an insertion wire 13 and to enable the supply of medical reagents such as by the use of a contrast agent to allow angiography to be performed during placement and deployment phases of the medical procedure. A thin walled metal tube 15 is fastened to the extension 11 and extends through the complete introducer to the manipulation section and terminates in a connection means 16 for a syringe so that the medical reagent may be introduced into the metal tube and subsequently the extension 11 to emanate through the apertures 14. The thin walled metal tube 15 is flexible so that the introducer can be advanced along a relatively tortuous vessel such as the femoral artery and also to allow manipulation longitudinally and rotationally of the proximal attachment region 3.
- 15 The prosthesis 20 is of a self expanding type having resilient stents 19 to enable it to expand after it is released from the introducer. The prosthesis retained within the introducer includes a self expanding zigzag stent 21 extending from its proximal end and in the compressed condition the zigzag stent 21 is retained in the cylindrical sleeve 10 of the proximal attachment region 3 and retained in there by means of a trigger wire 22 which extends through an aperture 23 in the side of the proximal attachment device 10 and is received in one of the loops of the zigzag stent. The trigger wire 22 extends along most of the length of the introducer and exits at the manipulation region at a proximal wire release mechanism 24.
- 25 The prosthesis 20 is retained in its compressed condition by means of an external sleeve 30 which is advanced to be received over the cylindrical sleeve 10 of the proximal attachment device 10 when the device is assembled for insertion as can be particularly seen in FIG 2. The external sheath 30 extends distally to external of a patient to the external manipulation section and a gripping and haemostatic sealing means 35 thereof.
- 30 As can be particularly seen in FIG 8, the distal end of the prosthesis 20 is retained in the distal attachment device 40 which is mounted onto a thick walled plastics tube 41 which extends distally to external of the patient and to the manipulation region 1. The thick walled tube is coaxial with and radially outside the thin walled tube 15 and the sheath 30 is coaxial with and radially

outside the thick walled tube 41. The distal end 42 of the prosthesis 20 has a loop 43 through which a distal trigger wire 44 extends. The distal trigger wire extends through an aperture 45 on the distal attachment device into the annular region between the thin walled tube 15 and the thick walled tube 41 like the proximal trigger wire which also extends through the annular space between the thick walled tubing 41 and the thin walled tubing 15 to the manipulation device and out at a distal wire release mechanism 25 as depicted in FIG 2.

In the alternative embodiment as shown in FIGS 8A and 8B, the thick walled tube 160 has a tapered end 161 through the thin walled tube 162 extends. A low friction lining 163 is provided between the thick walled tube 160 and the thin walled tube 162 so that the former slides easily over the latter. The proximal release wire 165 and the distal release wire 167 are within the thick walled tube 160 and extend out respective apertures 166 and 168 distal of the tapered portion 161. the distal release wire 167 passes through the loop 170 in the distal end of the prosthesis 171 and re-enters the tapered portion 161 through aperture 172.

As shown in FIG 8B when the distal attachment region has been advanced to the proximal attachment region the tapered portion 161 fits into the tube 175 to provide a smooth surface for the retraction of the two together.

As can be particularly seen in FIG 10 the haemostatic seal which remains external of a patient in use has a clamping collar 26 which clamps the external sleeve 30 to the haemostatic seal 27. The haemostatic seal 27 has a silicone seal ring 28 to seal against the thick walled tubing 41 to provide the haemostatic seal and a side tube 29 for the introduction of medical reagents between the thick walled tubing 41 and the external sleeve 30.

As can be particularly seen in FIG 11 the release wire actuation section of the external manipulation section has a body 36 into the end of which is mounted the thick walled tubing 41 and through which passes the thin walled tube 15. Both the proximal wire release mechanism 24 and the distal wire release mechanism 25 are mounted for slidable movement on the body 36. Their positioning is such that the proximal wire release mechanism 24 must be moved before the distal wire release mechanism 25 can be moved. This means that the distal end of the prosthesis cannot be released until the

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proximal end of the prosthesis has been released. Clamping screws 37 are provided on each of the proximal wire release mechanism 24 and distal wire release mechanism 25 to prevent inadvertent early release of either end of the prosthesis. A haemostatic seal 38 is provided so the respective release
5 wire can extend out through the body 36 to the respective release mechanisms.

As can be particularly seen in FIG 12 there is a pin vice 39 mounted onto the other end of the body 36 from the thick walled tube 41. The pin vice 39 has a screw cap 46 which when screwed in clamps vice jaws 47 against the thin
1 0 walled metal tube 15 so that the thin walled tube 15 can only move with the body 26 and hence the thin walled tube can only move with the thick walled tube 41. With the clamp tightened the entire assembly except the external sleeve 30 can be moved as one.

We now looking at FIG 2 to 7 which show the various stages of the
1 5 deployment of the prosthesis according to this embodiment of the invention.

A guide wire (not shown) is introduced into the femoral artery and advanced until its tip is above the region into which the prosthesis is to be deployed.

In FIG 2 the introducer assembly is shown fully assembled ready for introduction into a patient. The prosthesis 20 is retained at each of its ends
2 0 by the proximal and distal retaining assemblies respectively and compressed by the external sleeve 30. If it is an aortic aneurism which is to be grafted the introducer assembly can be inserted through a femoral artery over the guide wire in the form as shown in FIG 2 and positioned by radiographic techniques (not discussed here).

2 5 In FIG 3 it will be seen that once the introducer assembly is in a selected position the external sheath 30 is withdrawn to just proximal of the distal attachment device 40 so that the prosthesis 20 is now released so that it can expand radially except where the most proximal zigzag stent 21 is still retained within the proximal attachment device 10 and where its distal end 42
3 0 is retained within the external sheath 30.

By release of the pin vice 39 to allow small movements of the thin walled tubing 15 with respect to the thick walled tubing 41 the prosthesis 20 may

now be lengthened or shortened or rotated or compressed to accurately place in the desired place within the body lumen. X-ray opaque markers (not shown) may be placed at known places along the prosthesis to assist with placement of the prosthesis.

- 5 In FIG 4 the proximal trigger wire 22 (FIG 3) has been withdrawn by distal movement of the proximal wire release mechanism 24 (FIG 3). At this stage the proximal wire release mechanism 24 and the proximal trigger wire 22 have been removed completely by passing the proximal wire release mechanism 24 over the pin vice 39,46 and the connection means 16 for a
10 syringe. The screw cap 46 of the pin vice 39 has then been loosened so that the thin walled tubing 15 can be pushed in a proximal direction to move the proximal attachment means 10 in a proximal direction thereby releasing the zigzag stent 21 at the proximal end of the prosthesis from the proximal attachment means 10. At this stage the hooks or barbs 26 on the zigzag stent
15 21 grip into the walls of the lumen to hold the prosthesis therein. From this stage the proximal end of the prosthesis cannot be moved again.

- The distal end of the prosthesis 42 is still retained by the distal attachment means 40 with the loop 43 retained therein. The external sheath 30 has been withdrawn to distal of the distal attachment device 40 to allow the distal
20 end of the attachment device to expand.

- At this stage, however, the distal end of the prosthesis can still be moved so that the prosthesis can be rotated or lengthened or shortened or otherwise moved to accurately position the prosthesis. Where the prosthesis to be deployed is a bifurcated graft the movement at this stage can ensure that the
25 shorter leg is directed in the direction of the contra-iliac artery

- In FIG 5 the distal end 42 of the prosthesis has been released by removal of the distal trigger wire 44. At this stage the distal wire release mechanism 25 and the distal trigger wire 44 can be removed completely by passing the distal wire release mechanism 25 over the pin vice and the connection
30 means 16 for a syringe. The loop 43 of the terminal distal zigzag stent is hence freed and the prosthesis is now free to expand to the walls of the vessel and the introducer is ready to be removed.

The first stage of removal is shown in FIG 6 where the distal attachment

device 40 is advanced to be received in the rear of the proximal attachment device 10 and then the proximal attachment device 10 including the tapered flexible extension 11 and the distal attachment device 40 are removed together as shown in FIG 7. In this drawing the external sleeve 30 has been advanced to cover the join between the proximal attachment device 10 and the distal attachment device 40 and is also removed with the proximal attachment device 10, the tapered flexible extension 11 and the distal attachment device 40 although these could be removed separately and then the external sleeve 30 removed later. This may have some advantage if further surgical procedures are necessary as a clear way is provided to advance other surgical equipment.

FIGS 13A to FIG 13C shows the use of the introducer according to this invention with a self expanding bifurcated prosthesis

In FIGS 13A to FIG 13C the section of the introducer including the proximal attachment device and the distal attachment device of the introducer with a bifurcated prosthesis is shown.

The bifurcated prosthesis 50 is retained within the external sheath 51 between the proximal attachment device 52 and the distal attachment device 53 with respective fixings to the proximal attachment device 52 and the distal attachment device 53 of the same for as shown in Figs 1 to 12. The proximally extending zigzag stent 57 is retained within the proximal attachment device 52.

As shown in FIG 13B after the proximal trigger wire 61 has been released and the proximal attachment device 52 advanced the proximal end of 56 of the prosthesis 50 is released and the zigzag stent 57 is free to expand. At this stage the distal end 58 of the prosthesis 50 is still retained in the distal attachment means 53.

At this stage an extension piece 59 can be inserted into the side arm 60 by a separate introducer from the other femoral artery as shown in Fig 13C. The release of the distal attachment device and the withdrawal of the introducer can be proceed in the same manner as discussed with respect to Figs 1 to 12.

An embodiment of introducer according to this invention suitable for the introduction of an extension prosthesis is shown in FIG 14 which shows the various portions of the introducer along its length.

Commencing from the proximal end the embodiment includes a tapered flexible extension 70 mounted on a thin walled metal tube 71. The tapered flexible extension 70 includes a longitudinal aperture 73. The thin walled metal tube 71 is fastened to the tapered flexible extension and extends in a distal direction from the tapered flexible extension to external of the patient in use. The thin walled metal tube 71 extends to a connector 74 for the introduction of medical reagents as necessary. There are no proximal or distal attachment devices on the extension prosthesis introducer. The prosthesis 75 is retained between the distal end 80 of the flexible extension and the proximal end 78 of a thick walled flexible tube 77. A sheath 79 is a sliding fit on the thick walled tube 77 and during the insertion process is fitted over the extension prosthesis up to the distal end 80 of the flexible extension 70 to provide a smooth surface for the progression of the introducer through the vasculature.

The method of introduction of the extension prosthesis is as follows.

A guide wire (not shown) is introduced into the femoral artery and advanced until its tip is above the region into which the prosthesis is to be deployed. The introducer is then advanced over the guide wire with a oscillating rotating action until the extension prosthesis is overlapped one full stent within the shorter leg of the prosthesis. A final position check may than be made before the sheath 79 is withdrawn while holding the thick walled tube 77 in place. The introducer can then be removed by withdrawing the flexible extension 70 to the thick walled tube 77 and covering the gap between then with the sheath 79.

FIG 15 shows an embodiment of a bifurcated prosthesis with an extension prosthesis according to this invention. The bifurcated prosthesis 90 has a generally inverted Y- shaped configuration having a body portion 91, a shorter leg 92 and a longer leg 93. The body of the prosthesis is constructed from a tubular woven synthetic material such as dacron. At the proximal end 94 of the prosthesis 90 is a first zigzag stent 95 which extends beyond the end of the prosthesis and has distally extending barbs 96. The prosthesis

has a number of zigzag stents mounted to it and extending along its length. The stent 97 nearest the proximal end 94 is inside the tubular material so that the outside presents a smooth surface which in use engages against the inner wall of the vessel into which it is deployed to provide a barrier to the flow of blood. The stent 98 nearest the distal end 99 of the longer leg is also inside the tubular material so that the outside presents a smooth surface which in use engages against the inner wall of the vessel into which it is deployed to provide a barrier to the flow of blood. Between these internal stents the rest of the stents 100 are arranged on the outside of the tubular material so that they present minimal restriction to the flow of blood through the prosthesis and present minimal sites for the growth of thromboses within the prosthesis. Each stent is sewn to the tubular material as shown particularly at 101.

The longer leg 93 has one loop 43 of the terminal internal stent 98 extending beyond the end of the tubular material to act as the distal attachment means.

In use the prosthesis according to this embodiment of the invention is adapted for fitting into aorta such that the end 94 is just distal of the renal arteries and the first zigzag stent 95 extend up to or over the renal arteries. As it is constructed from thin wire it does not obstruct the renal arteries if it extends over them. The longer leg 93 extends down one of the iliac arteries and the shorter leg terminates in the aorta just short of the other iliac artery.

The terminal stent 102 nearest the distal end 92 of the shorter leg is outside the tubular material so that the inside presents a smooth surface which in use engages against the outside of one end of an extension prosthesis.

An extension prosthesis 104 is adapted for fitting into the shorter leg by the method as discussed above. The extension prosthesis 104 is constructed from a tubular synthetic material such as dacron and has terminal internal stents 105 and a plurality of external intermediate stents 106.

FIG 16 shows an embodiment of a bifurcated prosthesis with two extension prostheses according to this invention. The bifurcated prosthesis 110 has a generally inverted Y- shaped configuration having a body portion 111, a shorter leg 112 and a longer leg 113. The body of the prosthesis is constructed from a tubular woven synthetic material such as dacron. At the

- proximal end 114 of the prosthesis 110 is a first zigzag stent 115 which extends beyond the end of the prosthesis and has distally extending barbs 116. The prosthesis has a number of zigzag stents mounted to it and extending along its length. The stent 117 nearest the proximal end 114 is
- 5 inside the tubular material so that the outside presents a smooth surface which in use engages against the inner wall of the vessel into which it is deployed to provide a barrier to the flow of blood. The terminal stents 118 nearest the distal end 99 of the both the shorter and longer legs are outside the tubular material so that the inside presents a smooth surface which in use
- 10 engages against the outside of one end of an extension prosthesis. Between these terminal stents the rest of the stents 119 are arranged on the outside of the tubular material so that they present minimal restriction to the flow of blood through the prosthesis and present minimal sites for the growth of thromboses within the prosthesis.
- 15 The longer leg 113 has one loop 43 of the terminal external stent 118 extending beyond the end of the tubular material to act as the distal attachment means.

- Extension prostheses 120 and 121 are adapted for fitting into both the shorter and longer legs by the method as discussed above. Each of the extension
- 20 prostheses 120 and 121 are constructed from a tubular synthetic material such as dacron and have terminal internal stents 122 and a plurality of external intermediate stents 123.

- In use the prosthesis according to this embodiment of the invention is adapted for fitting into aorta such that the end 114 is just distal of the renal
- 25 arteries and the first zigzag stent 115 extend up to or over the renal arteries. As it is constructed from thin wire it does not obstruct the renal arteries if it extends over them. The longer leg 113 extends down one of the iliac arteries and the shorter leg terminates in the aorta just short of the other iliac artery. The extension prostheses when deployed extend down each iliac artery.

- 30 FIG 17 shows an embodiment of a prosthesis according to this invention intended for aortouni-iliac deployment. The prosthesis 130 has a generally tapering tubular configuration having a body portion 131 extending down to a single leg 132 of lesser diameter than the body portion. The body of the prosthesis is constructed from a tubular woven synthetic material such as

dacron. At the proximal end 134 of the prosthesis 130 is a first zigzag stent 135 which extends beyond the end of the prosthesis and has distally extending barbs 136. The prosthesis has a number of zigzag stents mounted to it and extending along its length. The stent 137 nearest the proximal end 134 is inside the tubular material so that the outside presents a smooth surface which in use engages against the inner wall of the vessel into which it is deployed to provide a barrier to the flow of blood. The stent 138 nearest the distal end 132 of the leg is also inside the tubular material so that the outside presents a smooth surface which in use engages against the inner wall of the vessel into which it is deployed to provide a barrier to the flow of blood. Between these internal stents the rest of the stents 140 are arranged on the outside of the tubular material so that they present minimal restriction to the flow of blood through the prosthesis and present minimal sites for the growth of thromboses within the prosthesis.

The leg 132 has one loop 43 of the terminal external stent 138 extending beyond the end of the tubular material to act as the distal attachment means.

In use the prosthesis according to this embodiment of the invention is adapted for fitting into aorta such that the end 134 is just distal of the renal arteries and the first zigzag stent 135 extends up to or over the renal arteries. As it is constructed from thin wire it does not obstruct the renal arteries if it extends over them. The leg 132 extends down one of the iliac arteries. The other iliac artery is intended to be closed off with a plug inserted via the femoral artery and a cross graft is surgically inserted between the iliac arteries to provide blood flow to both iliac arteries.

FIG 18 shows a deployed prosthesis according to the embodiment this invention within an aorta with an aneurism.

The aneurism 150 is a ballooning of the aorta 152 between the renal arteries 153 and the iliac arteries 154. The prosthesis as shown in FIG 15 is deployed into the aorta so that it spans the aneurism allows blood flow from the aorta to the two iliac arteries. It will be noted that the proximal portion 94 of the prosthesis 90 which has the stent on the inside bears against the wall of the aorta 152 above the aneurism so that a good seal is obtained. The zigzag stent 95 which extends beyond the portion 94 extends over the entrances to the renal arteries but as the wire of the stent is fine occlusion

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does not occur. The distal end of the prosthesis 99 seals against the wall of one of the iliac arteries and the distal end 155 of the extension prosthesis 104 bears against the wall of the other iliac artery.

- 5 The join 156 between the prosthesis 90 and the extension prosthesis 104 seals because there is a smooth connection between the smooth inner surface on the shorter leg 112 and the smooth outer surface of the proximal end of the extension prosthesis 104.

- 10 The size of the prostheses according to this invention may be selected so that there is in effect an interference fit in the sound parts of the vessels to give good sealing onto the inner walls of the vessels. The prosthesis at its widest may range in diameter from 20 mm to 32 mm where it fits into the aorta and from 8 mm to 24 mm where it fits into the iliac arteries.

- 15 The embodiment shown in FIG 15 may have an overall length of from 120 mm to 180 mm not counting the length of the uncovered proximal stent and the extension prosthesis may have a length of from 35 mm to 125 mm and a diameter of from 8 mm to 24 mm. The amount of overlap between the shorter leg of the prosthesis and the proximal end of the extension prosthesis is from 15 mm to 21 mm.

- 20 The embodiment shown in FIG 16 may have an overall length of from 100 mm to 130 mm not counting the length of the uncovered proximal stent. The difference in length between the shorter and longer legs of the bifurcated prosthesis may be 30 mm. The shorter extension prosthesis may have a length of from 65 mm to 125 mm and a diameter of from 8 mm to 24 mm. The amount of overlap between the shorter leg of the prosthesis and the proximal end of the longer extension prosthesis is from 15 mm to 22 mm. The longer extension prosthesis may have a length of from 35 mm to 125 mm and a diameter of from 8 mm to 24 mm. The amount of overlap between the longer leg of the prosthesis and the proximal end of the shorter extension prosthesis is from 15 mm to 22 mm.

- 30 The embodiment shown in FIG 17 may have an overall length of from 90 mm to 180 mm not counting the length of the uncovered proximal stent. The prosthesis at its widest may range in diameter from 20 mm to 32 mm where it fits into the aorta and from 8 mm to 24 mm where it fits into one of the iliac

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arteries

Throughout this specification unless the context requires otherwise, the words 'comprise' and 'include' and variations such as 'comprising' and 'including' will be understood to imply the inclusion of a stated integer or
5 group of integers but not the exclusion of any other integer or group of integers.

Throughout this specification various indications have been given as to the scope of this invention but the invention is not limited to any one of these but may reside in two or more of these combined together. The examples are
10 given for illustration only and not for limitation.

CLAIMS

1. An introducer for positioning an expandable endovascular prosthesis (20) in a lumen of a patient, the prosthesis having a proximal portion and a distal portion, the introducer comprising; a prosthesis positioning mechanism (2, 3) selectively releasable from the prosthesis when the prosthesis is positioned at a desired site in the lumen of a patient; a first control member (22, 24) controlling at least the longitudinal position of the proximal portion of the prosthesis; and a second control member (44, 25) controlling at least the longitudinal position of the distal portion of the prosthesis.
2. The introducer according to claim 1, wherein said prosthesis positioning mechanism includes a distal attachment region (2) and/or a proximal attachment region (3).
3. The introducer according to claim 2, wherein said distal attachment region includes a distal attachment device (10).
4. The introducer according to claim 2 or 3, wherein said proximal attachment region includes a proximal attachment device (10).
5. The introducer according to any one of claims 1 through 4, wherein the prosthesis positioning mechanism comprises a control arrangement. (15, 41) for controlling the length of the prosthesis.
6. The introducer according to any one of claims 1 through 4, wherein the prosthesis positioning mechanism comprises a rotational arrangement (15, 41) by which the relative angular orientation of the proximal and distal portions of the prosthesis can be adjusted.
7. The introducer according to any one of claims 1 through 4, wherein the prosthesis positioning mechanism comprises a rotational arrangement (15, 41) by which the angular orientation of the prosthesis can be adjusted.
8. The introducer according to any one of claims 1 through 7, wherein the introducer further comprises an expansion control mechanism (10, 30) controlling expansion of the prosthesis when the prosthesis is positioned at

the desired site in the lumen of the patient.

9. An endovascular arrangement for positioning an expandable prosthesis at a desired location in a lumen of a patient, said arrangement comprising a control section (1) to be maintained external to the patient, and
5 a prosthesis positioning mechanism (2, 3) controllable by the control section for moving and manipulating the prosthesis to a desired location in the lumen, wherein a first member (15) extends from the control section to a proximal region (3) of the positioning mechanism, the proximal region of the positioning mechanism having means (10) for controlling the proximal end of
10 the prosthesis, wherein a second member (41) extends from the control section to a distal region (2) of the positioning mechanism, the distal region having means (40) for controlling the distal end of the prosthesis in cooperation with the second member.
10. The endovascular arrangement according to claim 9, wherein the
15 arrangement further comprises contraction means for containing self expanding stents of the prosthesis during insertion of the prosthesis positioning mechanism into the lumen and/or expansion means for expanding expandable stents of the prosthesis when the prosthesis is positioned at the desired site in the lumen of the patient.
- 20 11. The arrangement according to claim 10, wherein the contraction means includes tubular means (30) that extends from the control section to the positioning mechanism and serves to contain the prosthesis during insertion of the positioning mechanism into the lumen and to control the distal end of the prosthesis when the tubular means has been moved in a distal direction
25 relative to the first and second members, relative movement between the first and second members enabling manipulation of the prosthesis when in the lumen.
12. The arrangement according to claim 10 or 11, wherein the
30 expansion means includes at least radial means for radially expandable stents of the prosthesis when the prosthesis is positioned at the desired location in the lumen.
13. The arrangement according to claim 12, wherein the expansion means includes an inflatable balloon.

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14. The arrangement according to claim 12, wherein the first and second members are contained within the said tubular means.
15. The arrangement according to claim 12 or 14, wherein means (39) are provided for clamping the first and second members together during insertion of the prosthesis and for releasing the first and second members prior to the manipulation.
16. The arrangement according to claims 12, 14, or 15 wherein expansion of a non self expanding prosthesis can be performed by expansion of a balloon located around the first member and within the prosthesis, said balloon being inflatable from the control section.
17. The arrangement according to claim 12, 14, 15, or 16, wherein the said proximal region of the attachment mechanism contains tubular means (10) for containing the proximal end of the prosthesis prior to final positioning thereof, and wherein release of the prosthesis from tubular means (10) is achieved by proximal movement of the first member.
18. The arrangement according to any one of claims 9 through 17, wherein the second member has means (40) for controlling the distal end of the stent whilst the latter is inside the tubular means (30).
19. The arrangement according to any one of claims 9 through 18, wherein the arrangement further comprises release mechanisms (24, 25) in the control section for controlling wires (22, 44) extending to respective stents of the prosthesis.
20. The arrangement according to any one of the claims 9 through 19, wherein the prosthesis positioning mechanism comprises a control arrangement (15, 41) for controlling the length of the prosthesis.
21. The arrangement according to any one of claims 9 through 19, wherein the prosthesis positioning mechanism comprises a rotational arrangement (15, 41) by which the relative angular orientation of the proximal and distal portions of the prosthesis can be adjusted.
22. The arrangement according to any one of claims 9 through 19,

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wherein the prosthesis positioning mechanism comprises a rotational arrangement (15, 41) by which the angular orientation of the prosthesis can be adjusted.

23. The arrangement according to any one of claims 9 through 19, wherein the introducer further comprises an expansion control mechanism (10, 30) for controlling expansion of the prosthesis when the prosthesis is positioned at the desired site in the lumen of the patient.

24. An introducer adapted for the introduction of a self expanding endovascular prosthesis into a lumen of a patient, the prosthesis having a proximal end and a distal end, the introducer comprising,
- a. a proximal attachment device adapted to be attached to the proximal end of the prosthesis,
 - b. distal attachment device adapted to be attached to the distal end of the prosthesis,
 - c. each of the proximal and distal attachment devices attaching to the prosthesis in such a manner that the prosthesis can be held in tension therebetween and that each end of the prosthesis can individually be moved in proximal and distal directions and be rotated, and
 - d. proximal releasing means associated with the proximal attachment device and distal releasing means associated with the distal attachment device to enable selective releasing of the proximal and distal ends of the prosthesis.

25. An introducer as in claim 24 wherein the proximal attachment means has a long flexible extension on its proximal end to facilitate insertion of the introducer into a body lumen and its advancement along the lumen.

26. An introducer as in claim 25 wherein the proximal attachment device is mounted on a flexible thin walled tube which extends in a distal direction from the proximal attachment device to an external manipulation section of the introducer which is adapted to remain external of the patient.

27. An introducer as in claim 26 wherein the thin wall metal tube includes fluid connection means external of the patient to enable the introduction of a medical reagent therethrough.

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28. An introducer as in claim 27 wherein the long flexible extension includes a hollow tube therethrough in fluid communication with the thin wall metal tube and a plurality of side holes to enable dispersion of the medical reagent proximal of the prosthesis.
- 5 29. An introducer as in claim 26 wherein the distal attachment device is mounted on a flexible thick walled tubing and coaxial on the thin walled tube and extending in a distal direction to the external manipulation section and mounted such that the respective tubes can be moved together or independently.
- 10 30. An introducer as in claim 29 including a haemostatic seal between the thin walled tube and the thick walled tube in the manipulation section.
31. An introducer as in claim 30 including means to introduce a medical reagent into an annular space defined between the thin walled tube and the thick walled tube.
- 15 32. An introducer as in claim 24 including a proximal trigger wire extending from the proximally attachment device to the manipulation section, the proximal trigger wire being adapted to activate the proximal releasing means.
33. An introducer as in claim 24 including a distal trigger wire extending
20 from the distal attachment device to the manipulation section, the distal trigger wire being adapted to activate the distal releasing means.
34. An introducer as in claim 24 including an external release mechanism for each of the proximal trigger wire and distal trigger wire, the external release mechanism adapted to prevent accidental release of the
25 trigger wires and to allow release of the distal releasing means only after release of the proximal releasing means.
35. An introducer as in claim 34 including a haemostatic seal around the respective trigger wires in the manipulation section.
36. An introducer as in claim 24 including an external sheath extending
30 from external of the patient to cover and compress the prosthesis during

insertion of the introducer into a patient and movable longitudinally from outside the patient to expose the prosthesis.

37. An introducer as in claim 36 wherein the external sheath is coaxial with and a sliding fit on the thick walled tube.

5 38. An introducer as in claim 37 wherein the external sheath has a proximal end which is tapered and smoothed to present a low resistance to advancement of the introducer during insertion.

39. An introducer as in claim 36 wherein the proximal end of the external sheath is adapted to have a tight fit on to the proximal attachment
10 device.

40. An introducer as in claim 24 wherein the distal attachment device is of a streamlined shape and is adapted to be advanced to the proximal attachment device whereby to allow smooth retrieval through the released prosthesis and into the external sheath for removal from a patient.

15 41. An introducer as in claim 24 wherein the prosthesis is a bifurcated prosthesis.

42. An introducer as in any one previous claim wherein the lumen of the patient is an aorta and the prosthesis is adapted to repair an aortic aneurism.

43. A method of placing a prosthesis into an internal lumen by means of
20 an insertion assembly the method including the steps of:

a. inserting the insertion assembly including the prosthesis into the internal lumen,

b. withdrawing a sheath from the insertion assembly to expose the prosthesis,

25 c. releasing the prosthesis from the insertion assembly,

d. replacing the sheath onto the insertion assembly, and

e. retracting the insertion assembly.

44. A method as in claim 43 wherein the prosthesis has a proximal end and a distal end and the insertion assembly includes a proximal attachment
30 device and a distal attachment device adapted to retain the proximal and

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distal ends of the prosthesis respectively and the step of releasing the prosthesis includes the steps of releasing the proximal end and then the distal end.

45. A method as in claim 44 wherein the step of replacing the sheath onto the insertion assembly includes the step of advancing the distal attachment device up to the proximal attachment device and withdrawing the two devices together.

46. A method as in claim 44 wherein between steps (b) and (c) the prosthesis is manipulated by respective movements of the proximal attachment device and distal attachment device to correctly position the prosthesis.

47. A method as in claim 43 wherein the prosthesis is a bifurcated prosthesis and the step of withdrawing the sheath includes the steps of withdrawing the sheath to a first position in which a side arm of the prosthesis is exposed, insertion of an extension prosthesis into the side arm and then full removal of the sheath from the prosthesis.

48. A method as in claim 47 wherein the step of insertion of the extension prosthesis into the side arm comprises the steps of;

- (f) inserting an extension insertion assembly into the side arm, the extension insertion assembly including a top guide mounted on a catheter, an extension prosthesis on the catheter and a sheath retaining the extension prosthesis and extending over the top guide,

(g) withdrawing the sheath to expose and deploy the extension prosthesis,

- (h) withdrawing the sheath, top guide and catheter together.

49. A method as in claim 48 wherein the top guide includes a long proximal nose extension.

50. A method as in claim 48 wherein the catheter includes a distal stop and the extension prosthesis is mounted between the distal stop and the top

guide.

51. A method as in claim 43 wherein the prosthesis is a bifurcated prosthesis and the step of withdrawing the sheath includes the steps of withdrawing the sheath to a first position in which a first side arm of the prosthesis is exposed, insertion of a first extension prosthesis into the first side arm, then full removal of the sheath from the prosthesis to expose a second side arm and then insertion of a second extension prosthesis into the second side arm.

52. A method as in claim 51 wherein the step of insertion of the first extension prosthesis into the side arm comprises the steps of;

(f) inserting a first extension insertion assembly into the first side arm, the first extension insertion assembly including a top guide mounted on a catheter, an extension prosthesis on the catheter and a sheath retaining the extension prosthesis and extending over the top guide,

- (g) withdrawing the sheath to expose and deploy the extension prosthesis,

(h) withdrawing the sheath, top guide and catheter together

and the step of insertion of the second extension arm includes the steps of ;s

- (i) inserting a second extension insertion assembly into the second side arm, the second extension insertion assembly including a top guide mounted on a catheter, an extension prosthesis on the catheter and a sheath retaining the extension prosthesis and extending over the top guide,

(j) withdrawing the sheath to expose and deploy the extension prosthesis,

- (k) withdrawing the sheath, top guide and catheter together..

53. A method as in claim 52 wherein each of the top guides includes a long proximal nose extension.

3 2

54 A method as in claim 52 wherein each of the catheters includes a distal stop and the extension prostheses are mounted between the distal stop and the top guide.

55. An intraluminal prosthesis having a tubular graft and a plurality of self expanding stents along the length of the graft the prosthesis having a
5 proximal end and a distal end, the prosthesis being characterised by the stents at the proximal end and at the distal end being inside the tubular graft and the remainder of the stents being on the outside of the graft.

56. An intraluminal prosthesis as in claim 55 further including a further
10 self expanding stent mounted to the proximal end of the graft and extending beyond the said proximal end.

57. An intraluminal prosthesis as in claim 56 when the further stent includes attachment devices.

58. An intraluminal prosthesis as in claim 57 wherein attachment
15 devices comprise barbs extending towards the distal end of the prosthesis.

59. An intraluminal prosthesis as in claim 55 wherein the prosthesis is bifurcated at its distal end to provide a shorter prosthesis leg and a longer prosthesis leg.

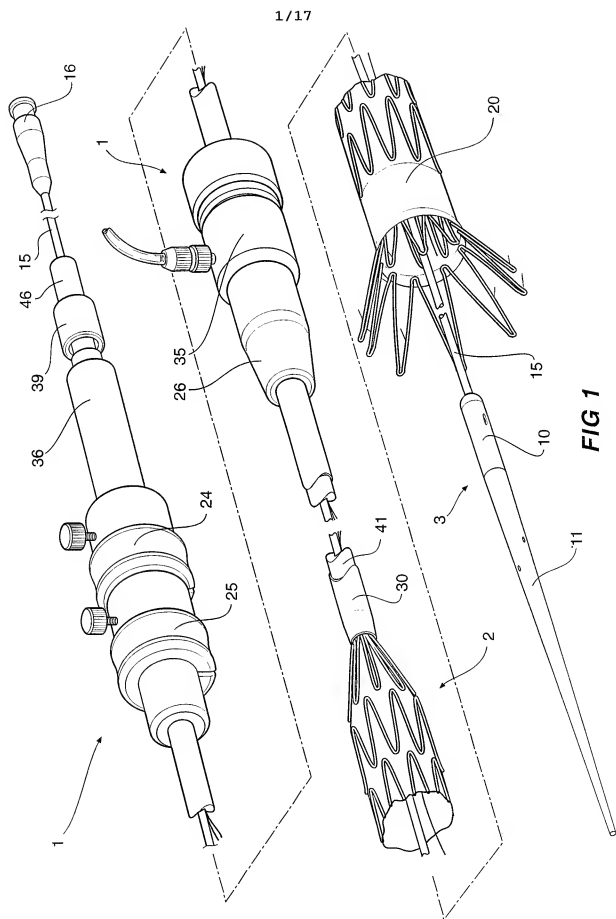
60. An intraluminal prosthesis as in claim 55 wherein the shorter leg has
20 a terminal stent on the outside of the prosthesis and the longer leg has the internal distal stent.

61. An intraluminal prosthesis as in claim 59 or 60 further including an extension prosthesis for insertion into the shorter prosthesis leg, the extension prosthesis comprising a tubular extension prosthesis and a
25 plurality of self expanding stents, the extension prosthesis having a proximal end and a distal end, stents at the proximal and distal ends being inside the tubular extension prosthesis and the remaining stents being on the outside of the prosthesis.

62. An intraluminal prosthesis as in claim 56 wherein both the shorter
30 leg and longer leg have external terminal stents and extension prostheses for

- each leg, each extension prosthesis comprising a tubular extension prosthesis and a plurality of self expanding stents, the extension prosthesis having a proximal end and a distal end, stents at the proximal and distal ends being inside the tubular extension prosthesis and the remaining stents being
- 5 on the outside of the prosthesis.

63. An intraluminal prosthesis as in claim 55 wherein each stent is a zig-zag stent.



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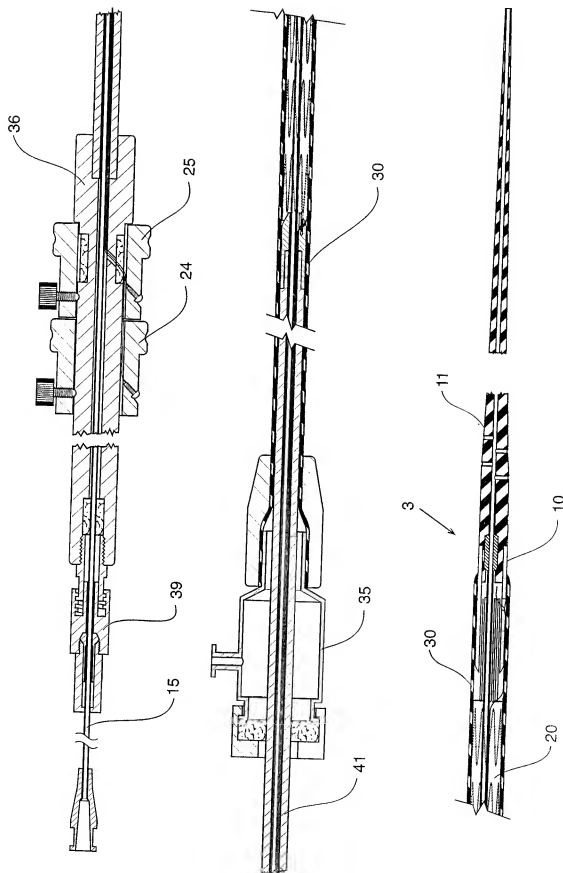
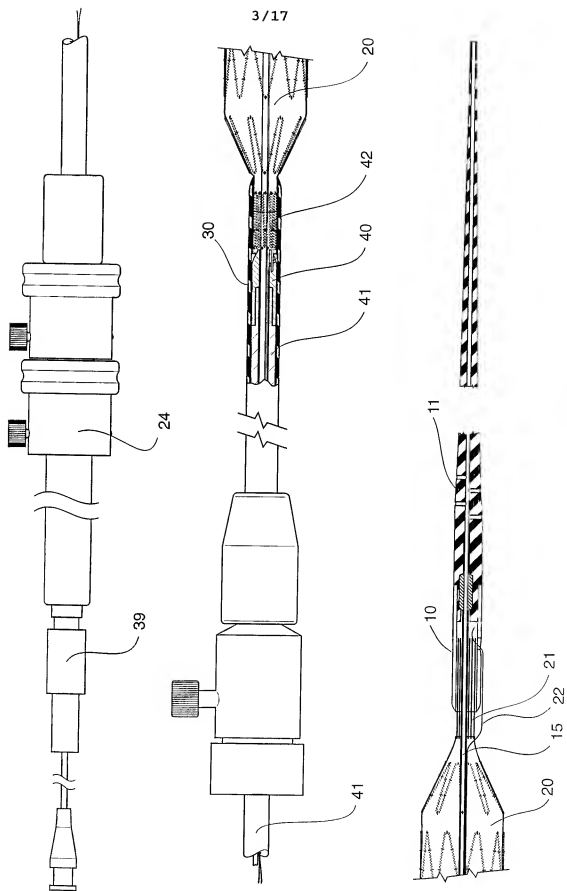
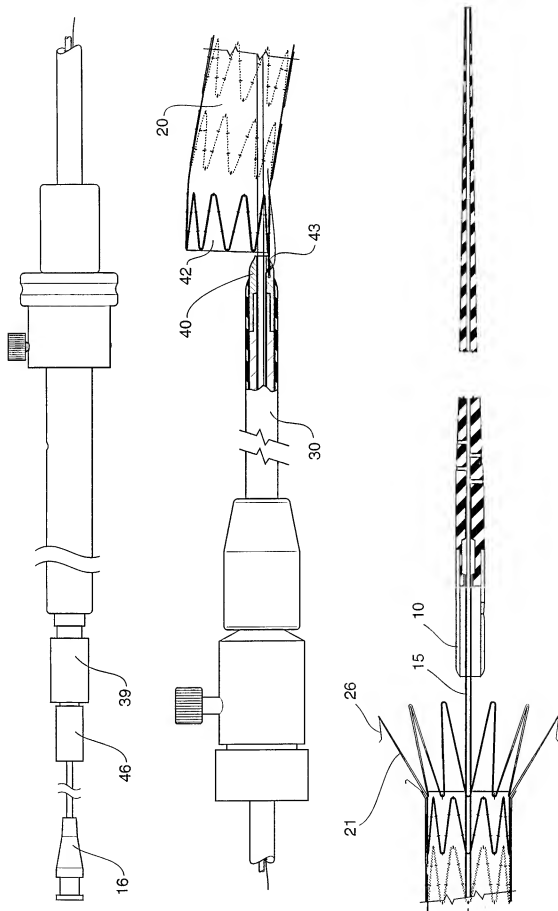


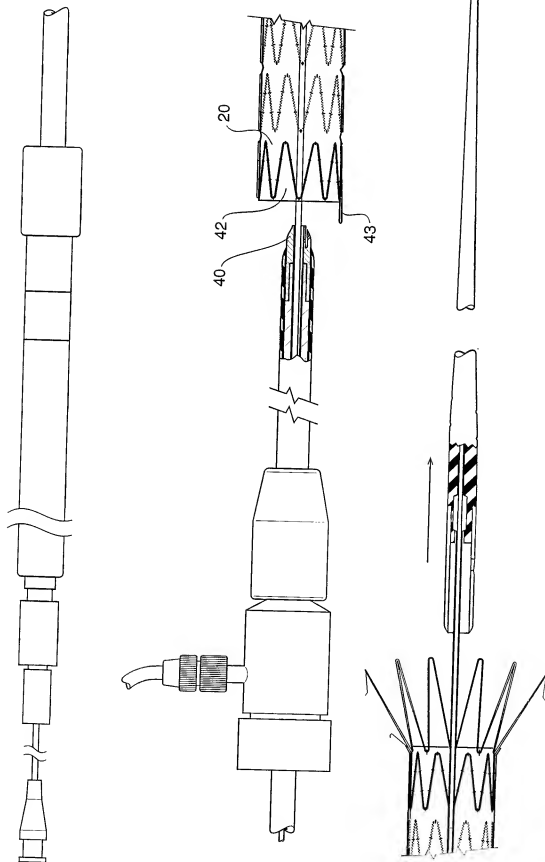
FIG 2



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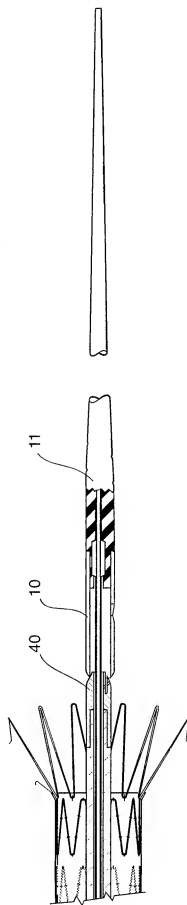
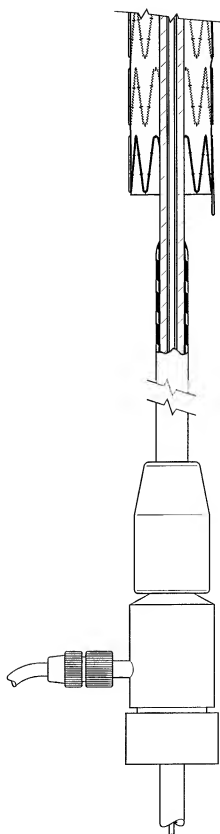
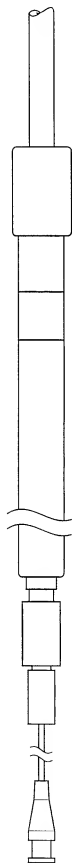
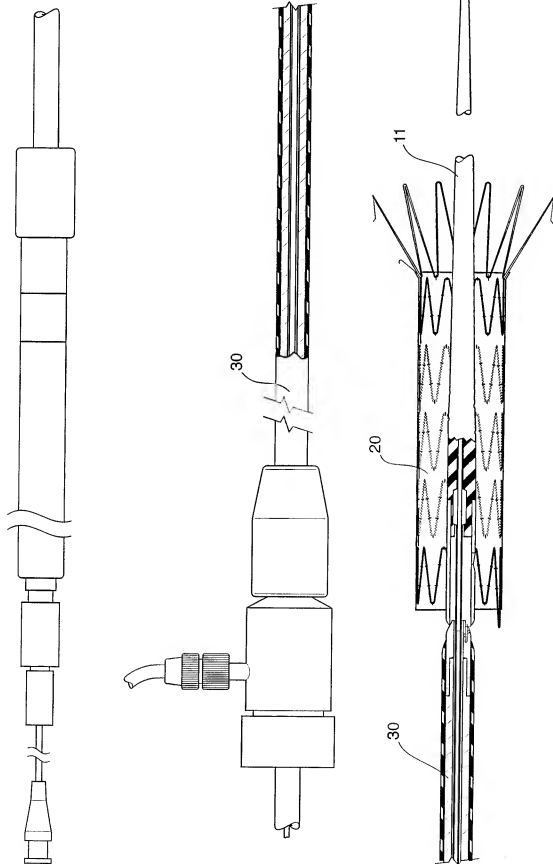


FIG 6

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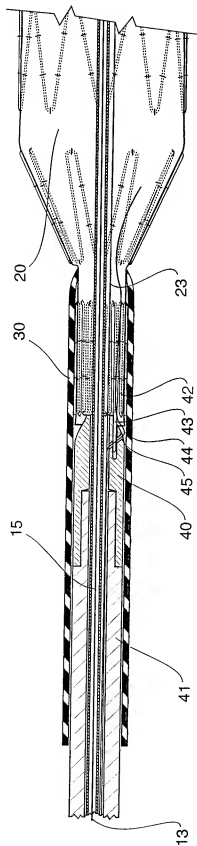


FIG 8

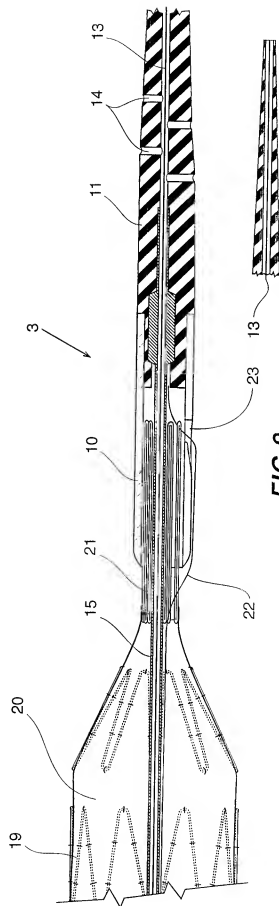
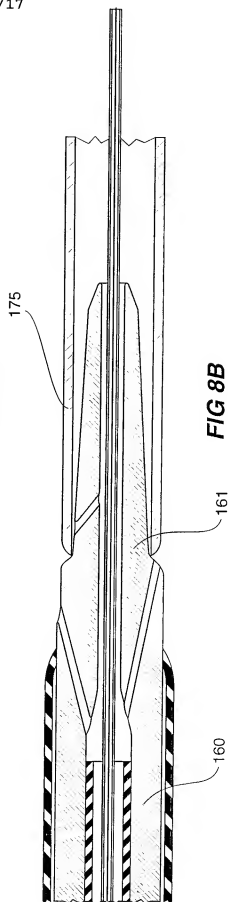
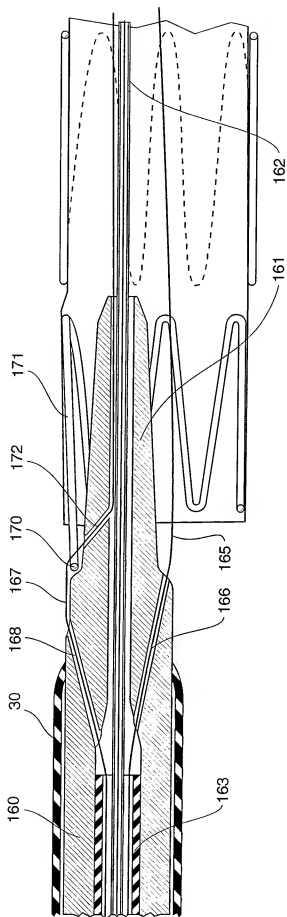
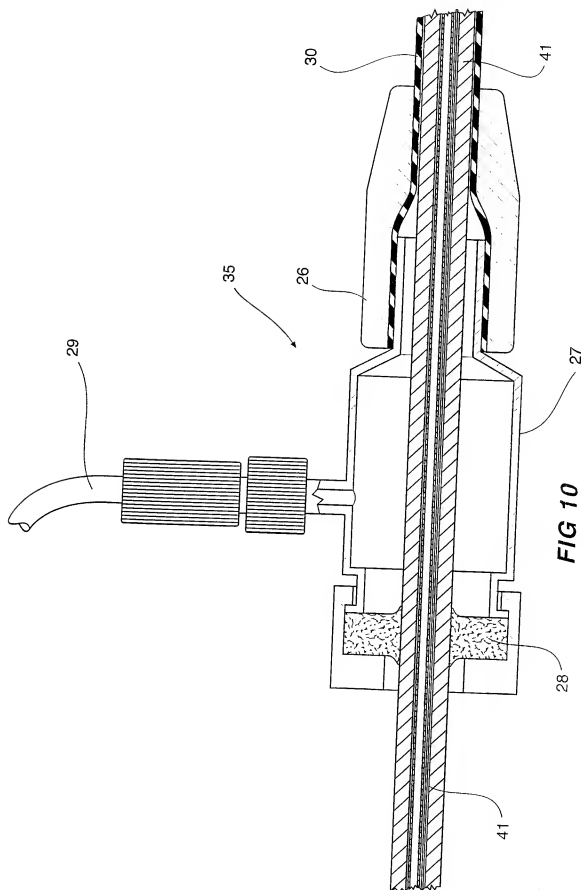


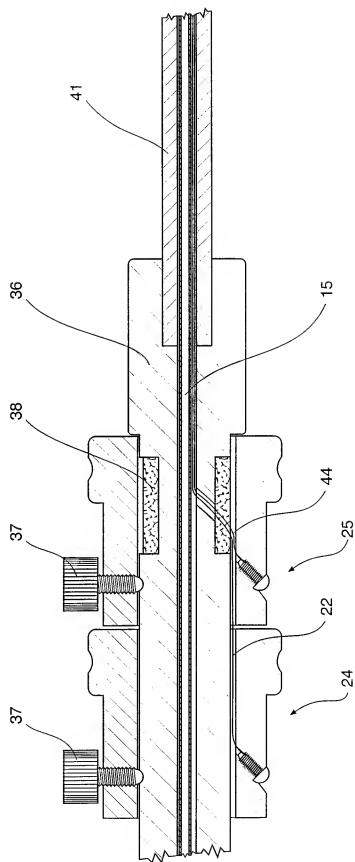
FIG 9



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**FIG 11**

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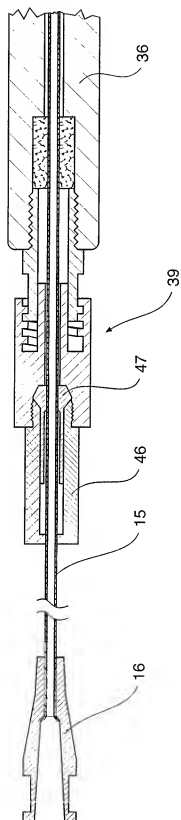


FIG 12

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FIG 13A

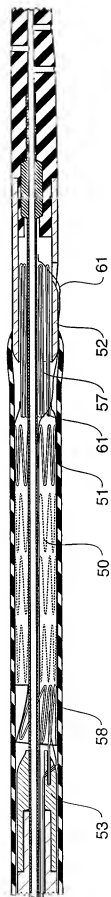
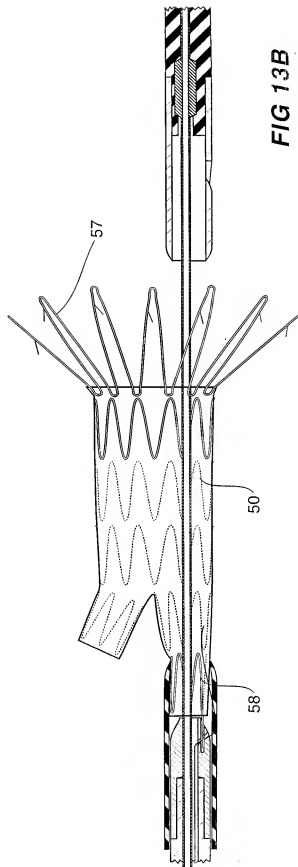
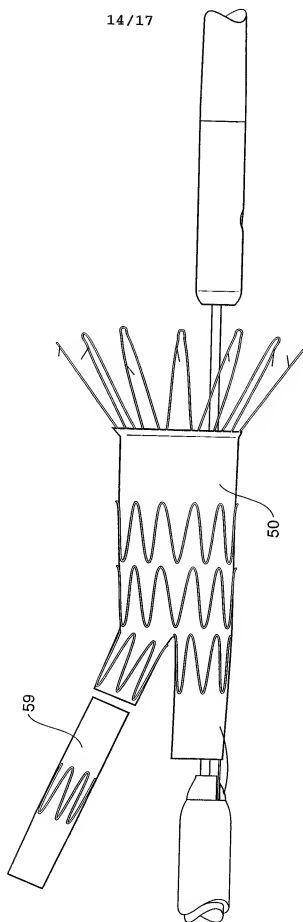


FIG 13B





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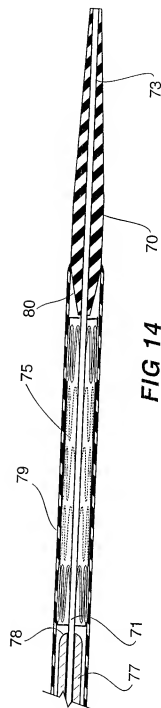
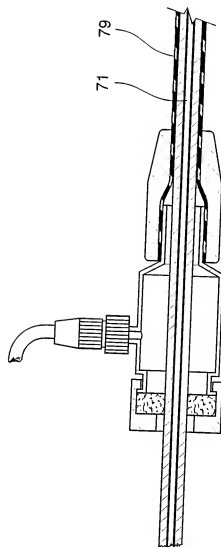
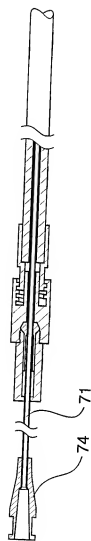
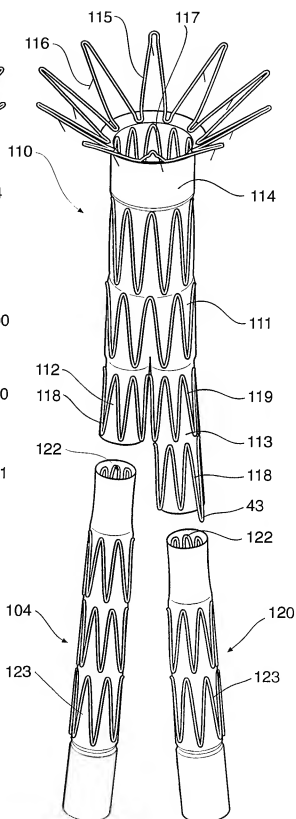
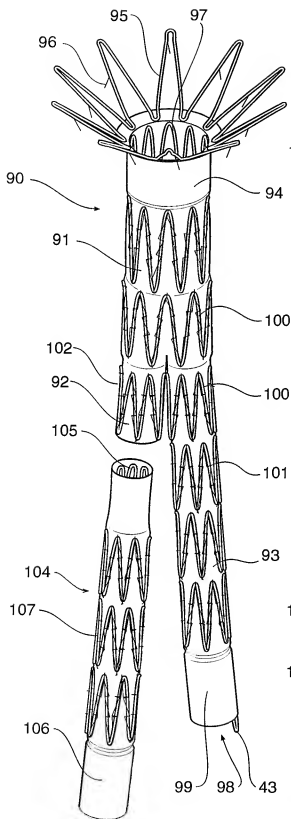
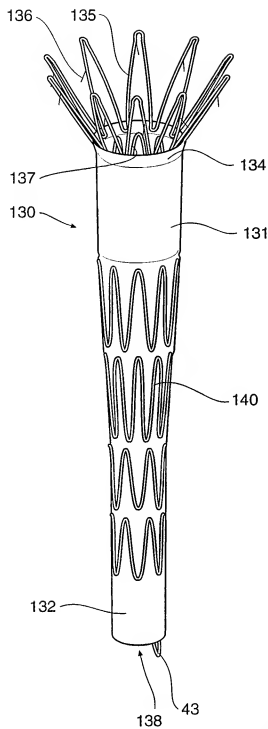
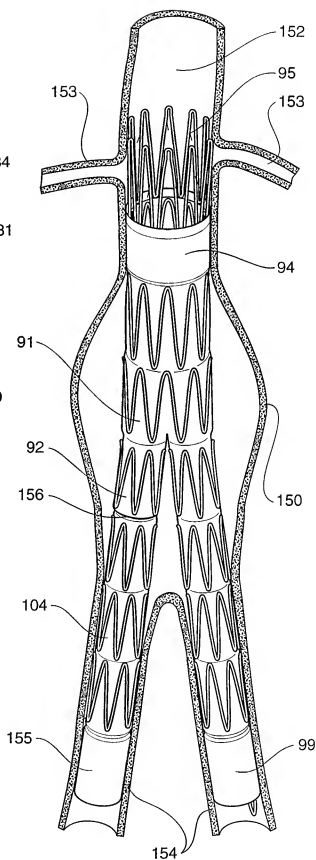


FIG 14

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**FIG 17****FIG 18**

A. CLASSIFICATION OF SUBJECT MATTERInt Cl⁶: A61F 2/06; A61M 29/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC: A61F; A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

AU IPC: A61F 2/06

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPAT: introduce emplace, deploy, sheath, sleeve cover

JAPIO: endovascular vein arter, prosthesis: graft

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 461791 A1 (BARONE et al) 18 December 1991 entire document	43,47-54
X	EP 637454 A1 (ENDOVASCULAR TECHNOLOGIES INC) 8 February 1995 column 19 line 23 to column 22 line 39 figures 27 to 83	1-4,8,43
X	EP 684022 A2 (ENDOVASCULAR TECHNOLOGIES INC) 29 November 1995 column 29 line 8 to column 34 line 31, figures 29 to 36	1-4,8,43,47-54
P,X	EP 795305 A2 (ENDOVASCULAR TECHNOLOGIES INC) 17 September 1997 entire document	43,47-54



Further documents are listed in the continuation of Box C



See patent family annex

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Date of the actual completion of the international search

21 July 1998

Date of mailing of the international search report

24 JUL 1998

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INTERNATIONAL SEARCH REPORT

International Application No.

PCT/AU 98/00383

C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5415664 A (PINCHUK) 16 May 1995 column 3 lines 21 to 63, column 7 line 64 to column 9 line 45, figures 9 to 116	1-4,43
P,X	US 5634941 A (WINSTON et al) 3 June 1997 column 4 line 20 to column 6 line 17, figures 5 to 7	43, 47-54
X	WO 96/24308 A (COOK INCORPORATED) 15 August 1996 entire document	1-4,8,43,47-54
P,A	WO 98/07388 A (SCIMED LIFE SYSTEMS, INC) 26 February 1998	
Y	WO 96/38101 A (MEADOX MEDICALS, INC) 5 December 1995 page 6 line 8 to page 8 line 9, figures	55-58,63
Y		59-62
Y	US 5122154 A (RHODES) 16 June 1992 figure 1	55-58,63
Y	FR 2722678 A (B BRAUN CELSA SA) 26 January 1996 figures	59-62
A	WO 96/33672 A (IMPRA, INC) 31 October 1996 page 13 line 4 to page 14 line 8, figure 1	55
A	EP 712614 A (ADVANCED CARDIOVASCULAR SYSTEMS INC) 22 May 1996 figures 9 to 11, column 11 line 17 to column 13 line 39	55

INTERNATIONAL SEARCH REPORTInternational Application No.
PCT/AU 98/00383**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Claims 1 to 42 relate to introducing a vascular prosthesis such that the position of the distal and proximal ends of the prosthesis may be manipulated. Claims 43 to 54 define a method wherein a sheath is positioned over a prosthesis prior to insertion at a bifurcated site, removed to place the prosthesis and replaced to remove the introducer. Claims 55 to 63 relate to a prosthesis with stents on the inside at the proximal and distal ends.

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No.

PCT/AU 98/00383

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Patent Document Cited in Search Report				Patent Family Member			
EP	461791	AU	78092/91	AU	77546/94	BR	9102548
		CA	2043562	JP	4231954	US	5360443
		ZA	9104248	US	5578072	US	5571173
		US	5578071	US	5591229	US	5643208
		US	5693087	US	5522880	US	5571171
		US	5683452	AU	74328/94	AU	16615/97
		AU	16617/97	AU	16618/97	BR	9403662
		CA	2132815	EP	646365	JP	8047503
		ZA	9407492				
EP	637454	AU	64747/94	AU	74253/96	CA	2125258
		JP	7059802	US	5749920	US	5693083
		US	4787899	US	5104399	US	5275622
		US	5397345	US	5562728	US	5662700
		US	5669936	AU	34392/89	AU	38261/93
		AU	40886/96	CA	1335528	EP	407425
		EP	688544	JP	3503246	WO	89/08433
		AU	80417/91	AU	70204/94	AU	12219/97
		CA	2046974	EP	466518	EP	680734
		IL	98820	JP	5076554	AU	46847/96
		CA	2207596	EP	797415	WO	96/18361
EP	684022	AU	71438/94	AU	62193/96	CA	2130138
		JP	8038486	US	5628783	US	5769885
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Information on patent family members

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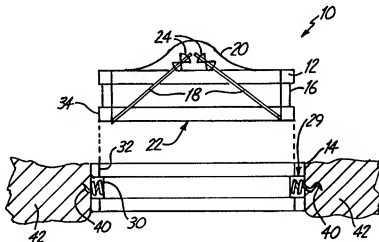
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Patent Document Cited in Search Report				Patent Family Member			
WO	96/33672	AU	54353/96	EP	822789	US	5667523
EP	712614	AU	37831/95	CA	2162956	JP	8336597

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification⁶ : A61B 17/064, 17/068, A61F 2/24</p>	<p>A1</p>	<p>(11) International Publication Number: WO 99/53845</p> <p>(43) International Publication Date: 28 October 1999 (28.10.99)</p>
<p>(21) International Application Number: PCT/US99/08817</p> <p>(22) International Filing Date: 19 April 1999 (19.04.99)</p> <p>(30) Priority Data: 09/062,822 20 April 1998 (20.04.98) US 09/203,169 1 December 1998 (01.12.98) US</p> <p>(71) Applicant: ST. JUDE MEDICAL, INC. [US/US]; One Lillehei Plaza, Saint Paul, MN 55117 (US).</p> <p>(72) Inventors: BUCHANAN, Eric, S.; 4905 Tri Oaks Circle South, Wyoming, MN 55092 (US). ANDERSON, Kimberly, A.; 956 Coneflower Court, Eagan, MN 55123 (US).</p> <p>(74) Agents: CHAMPLIN, Judson, K.; Westman, Champlin & Kelly, P.A., International Centre, Suite 1600, 900 Second Avenue South, Minneapolis, MN 55402-3319 (US) et al.</p>		<p>(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>

(54) Title: DRIVER TOOL FOR HEART VALVE PROSTHESIS FASTENERS



(57) Abstract

A driver tool (210) which drives helical fasteners (214) through a heart valve component (212) into tissue (213). The tool (210) has a tool housing (216) with a distal end (218) couplable to engage the implanted component (218). A drive shaft (222) at the proximal end of the driver tool (210) couples to a driving force. Multiple driver tips (266) couple to helical fasteners (214) for the heart valve component (212).

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-1-

DRIVER TOOL FOR HEART VALVE PROSTHESIS FASTENERS**FIELD OF THE INVENTION**

The present invention relates to mechanical heart valve prostheses. More specifically, the invention relates to a driver tool for attaching and implanting heart valve prostheses.

BACKGROUND OF THE INVENTION

Implantable mechanical heart valves are used for replacement of defective valves in hearts of patients. One common method employs a sewing ring or suture cuff which is attached to and extends around the outer circumference of the mechanical valve orifice. The sewing cuff is made of a biocompatible fabric suitable for allowing a needle and suture to pass therethrough. The valves are typically sutured to a tissue annulus that is left when the surgeon removes the existing valve from the patient's heart. The sutures are tied snugly, thereby securing the valve to the heart.

Sewing cuffs are labor intensive, difficult to manufacture and may be difficult to secure to the valve orifice. Further, attaching the suture cuff to the tissue annulus is time consuming and cumbersome. The complexity of suturing requires a patient to be on cardiopulmonary bypass for a lengthy period. It is also desirable to provide a large lumen through the valve orifice relative to the overall valve diameter for blood flow. However, techniques for attaching the sewing cuff to the valve orifice typically require that the area of the valve lumen be reduced to accommodate an attachment mechanism. For example, the sewing cuff is typically retained between two rims of the valve orifice. One of the rims normally defines the outside diameter of the

-2-

valve orifice and thus limits the size of the valve lumen.

Another technique for attaching heart valves uses a series of pins which pierce the tissue annulus of the heart. The pins are crimped or bent, thereby locking the valve to the heart tissue and preventing the valve from separating from the heart. This technique is described in U.S. Patent Nos. 3,574,865 and 3,546,710. Another technique for attaching a prosthetic heart valve to the heart tissue is shown in U.S. Patent No. 4,705,516 in which an outer orifice ring is sutured to the tissue annulus and an inner orifice ring is then screwed into the outer orifice ring. However, the rings are not locked together and may become unscrewed after extended use.

Implantable heart valves can require fasteners to hold them securely to surrounding tissue in the body. Suturing has been used. However, the use of suturing is time consuming and increases the duration of the implantation surgical procedure. The use of helical fasteners or screws is disclosed in the above cited pending application. However, access one at a time to the multiple helical fasteners used with an implant can be difficult and time consuming. The fasteners face in different directions and a simple tool must be positioned multiple times to approach the implantable heart valve component from several difficult angles around the heart, some of which may be obstructed by adjoining tissue. There is a need for an improved technology for screwing helical fasteners through a heart valve component into a tissue annulus of the heart.

-3-

SUMMARY OF THE INVENTION

The present invention is useful in implanting a prosthetic heart valve in a heart with helical fasteners. The heart valve includes an outer ring for coupling to a tissue annulus of a heart. An inner orifice ring includes an occluding mechanism movable between an open position, which allows blood flow through the lumen, and a closed position which prevents blood flow through the lumen. The inner orifice ring is adapted to be coupled to the outer orifice ring after the outer orifice ring has been attached to the tissue annulus. The outer ring is attached to the tissue annulus by helical screws and is coupled to the inner orifice ring by a snap fit.

In the present invention, a driver tool drives multiple helical fasteners simultaneously through the outer ring of a heart valve component into the surrounding tissue annulus of a heart. The driver tool includes a tool housing and has a distal end couplable to engage the heart valve component and a proximal end spaced from the distal end. A drive shaft at the proximal end is couplable to a driving force. A plurality of driver tips extend from the distal end, each driver tip coupling to a helical fastener for the heart valve. A drive train in the tool housing couples to the drive shaft to distribute driving force to each of the driver tips.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is an exploded cross-sectional view of a prosthetic heart valve.

Figure 2 is a cross-sectional view of the heart valve of Figure 1.

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Figure 3 is a perspective view of an attachment mechanism for the prosthetic heart valve of Figures 1 and 2.

Figure 4 is a side cross-sectional view of an
5 implantation tool for implanting the heart valve prosthesis shown in Figures 1 and 2.

Figure 5 is a side cross-sectional view of the tool of Figure 4 in which a holder portion of the tool is moved to an open position.

10 Figure 6 is a side perspective view of an outer orifice ring in accordance with another embodiment.

Figure 7A is a side plan view and Figure 7B is a side cross-sectional view of the outer orifice ring
15 shown in Figure 6.

Figure 8 is a side perspective view of a suture securing tool.

Figure 9 is a perspective view of a holder for use in implanting an outer ring of a heart valve.

20 FIG. 10 is a side cross sectional view of a driver tool engaging a heart valve outer ring and coupled to helical fasteners in accordance with the present invention.

FIG. 11 is a side cross sectional view of a
25 driver tool engaging a heart valve outer ring and coupled to helical fasteners in accordance with the present invention.

FIG. 12 is an enlarged cross sectional view of the distal end of the driver tool of FIGS. 10 or 11.

30 FIG. 13 is an end view of a distal end of the driver tools of FIGS. 10 and 11.

FIG. 14 is a cross sectional view along line 14-14 of FIG. 12.

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FIG. 15 is an enlarged cross sectional view of an alternate distal end of the driver tools of FIGS. 10 and 11.

FIG. 16 is a further enlarged cross sectional view of a portion of the alternate distal end of the driver tool of FIG. 15.

FIG. 17 is an enlarged cross sectional view of an alternate distal end of the driver tools of FIGS. 10 and 11.

FIG. 18 is an enlarged drawing of front and end views of a helical screw fastener with its last coil turned into the center of the coil.

FIG. 19 is an enlarged drawing of a front and an end view of a driver tip for use with the helical screw fastener of FIG. 18.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Heart valve prosthesis 10 shown in Figure 1 includes inner orifice ring 12 and outer orifice ring 14. Figure 1 is a side cross-sectional exploded view of valve 10 and Figure 2 is a side assembled cross-sectional view of valve 10.

Inner orifice ring 12 includes locking recess 16 (or, in another embodiment, a ridge) formed around its outer circumference. Leaflets (or occluders) 18 provide an occluding mechanism and are pivotably coupled to ring 12 at pivot guard 20. Leaflets or occluders 18 move between an open position (not shown) and a closed position as shown in Figures 1 and 2 in which flow of fluid through lumen 22 is blocked. Leaflets 18 rotate within pivots 24 formed in pivot guards 20. In one preferred embodiment, inner ring 12 comprises a prosthetic heart valve available from St. Jude Medical, Inc. of St. Paul, Minnesota, without a sewing cuff

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carried thereon. However, in some embodiments it may be preferable to use a specially designed inner ring 12.

Outer orifice ring 14 includes locking ridge 30 (or, in another embodiment, a recess) formed on an inner annulus circumference thereon. Inner annulus 32 of ring 14 is sized to have approximately the same radius as outer annulus 34 of inner ring 12. Similarly, locking ridge 30 of outer ring 14 substantially conforms to locking recess 16 of inner ring 12. Locking recess 16 and locking ridge 30 cooperate to provide a ring coupling mechanism adapted to couple the outer orifice ring to the inner orifice ring. Outer orifice ring 14 also includes tissue annulus attachment locking mechanism 40 which, in one preferred embodiment, comprises helical screws carried through holes 29 around the circumference of outer ring 14. Other types of attachment mechanisms include staples, pins, rivets, "nails", barbs, hooks, etc. These mechanisms could be coupled to or integral with the outer orifice ring. As illustrated in Figures 1 and 2, locking mechanism 40 attaches to the natural heart tissue annulus 42 of the patient.

In FIG. 3 a perspective view of locking mechanism 40 is shown in greater detail. Locking mechanism 40 is a helical screw preferably made of a biocompatible material. For example, locking mechanism 40 may be formed from a platinum-iridium alloy, MP35N (a wrought cobalt-nickel-chromium-molybdenum alloy), stainless steel, titanium or other biocompatible materials. As shown in Figure 3, tool 44 includes engaging tip 46 which fits into screw head 48. Locking mechanism 40 may be turned by rotating tool 44. In one embodiment, there are between 8 and 16 substantially

-7-

equally spaced locking mechanisms 40 around the circumference of inner orifice ring 12. However, any number may be used. Locking mechanism 40 typically extends between about .050 to about .200 inches into the tissue annulus 42.

Figure 4 is a side cross-sectional view of tool 60 for use in snapping inner ring 12 into outer ring 14 of heart valve prosthesis 10 shown in Figures 1 and 2. Tool 60 includes elongated handle 62 including proximal gripping end 64. Actuator rod 66 extends through a center opening 68 in handle 62. Holder 70 is coupled to a distal end of handle 62. Holder 70 includes moveable half 72A and fixed half 72B coupled at pivot 74. Halves 72 include lower lip 76 adapted to abut outer ring 14. Distal end 80 of actuator rod 66 couples to actuator cable 82 which is connected to half 72A. Spring 84 is coupled to actuator rod 66 and pushes actuator rod 66 in an axial direction away from holder 70 holding halves 72 in the closed position as shown in Figure 4. Rod 66 includes actuator button 90. Proximal end 64 of handle 62 includes handle grip 93.

Orifice pushing mechanism 91 is aligned axially with handle 62 and coupled to handle 62 by threads 92. Mechanism 91 includes gripping portion 94 and orifice abutting surface 96. As shown in Figure 4, orifice abutting surface 96 is adapted to abut inner orifice ring 12.

Figure 5 is a side cross-sectional view of a portion of tool 60 showing holder 70 in an open position in which half 72A is rotated about pivot 74. In this position, heart valve prosthesis 10 is freed from holder 70 such that heart valve prosthesis may be selectively removed from, or engaged with holder 70.

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In operation, pressure is applied to actuation button 90 while grasping handle grip 93. This causes actuator rod 66 to move downward, towards the distal end of tool 60 whereby cable 82 causes half 72A to rotate about pivot 74. When pressure is released from actuator button 90, spring 84 pushes actuator rod 66 in a direction away from holder 70 such that half 72A is moved back into a closed position by cable 82 as shown in Figure 4. After outer orifice ring 14 has been attached to the natural tissue annulus of the patient's heart, tool 60 containing pre-loaded ring 12 is inserted through implantable ring 14 by depressing actuator button 90. This engages lip 76 under ring 14. Mechanism 94 is then rotated whereby lip 76 and surface 96 work in opposing directions such that no axial force is applied to helical screws 40 or the patient's tissue annulus. Outer orifice ring 14 is held against lower lip 76 such that a relative pressure is applied between rings 12 and 14. This causes locking ridge 30 to seat within locking recess 16. When inner ring 12 has been "snapped" in place with ring 14, ring 12 prevents locking mechanisms 40 from unscrewing or disengaging. Force may then be applied to actuator button 90 such that half 72A of holder 70 rotates as shown in Figure 5 so that tool 60 may be removed from prosthesis 10.

Figure 6 is a perspective view of outer orifice ring 100 in accordance with another embodiment which is coupled to suture cuff 102. In the embodiment of Figure 6, ring 100 includes a plurality of suture holes 104 formed therein for receiving sutures 106. Further, the inner annulus of ring 100 includes suture receiving groove 108. Figure 7A is a side plan view of outer ring 100 and Figure 7B is a side cross-sectional

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view of outer ring 100. As shown in Figure 7A, the outer annulus of ring 100 includes cuff retaining grooves 110 formed therein. In one preferred embodiment, O-rings 101 are provided to prevent leakage
5 between the orifice rings as shown in Figure 7B. Retaining sutures are wound circumferentially through cuff 102 and within cuff retaining grooves 110 binding or clamping cuff 102 to ring 100.

Ring 100 is sutured to tissue annulus 42 using
10 sutures 106 which extend radially through cuff 102 and suture holes 104. Preferably, sutures 106 are metal sutures of a biocompatible material such as stainless steel. After the sutures 106 are threaded through the patient's natural tissue annulus and outer orifice ring
15 100, the surgeon secures the suture using knots 114 which may be formed by twisting the suture 106 as shown in Figure 6. Excess suture material is then trimmed and knots 114 are folded into suture grooves 108.

Figure 8 is a side perspective view of a
20 suture securing tool 130 for use in twisting sutures 106 shown in Figure 6. Tool 130 includes elongated body 132 carrying shaft 134 therethrough between an actuator 136 and a hook 138. Spring 140 pushes on end cap 144 and body 132 such that hook 138 presses against end cap 142.
25 By pressing on actuator 136, hook 138 may be extended to hook both ends of suture 106. When actuator 136 is released, suture 106 is trapped between hook 138 and cap 142. Tool 130 is then rotated to twist sutures 106 together forming twisted knots 114 shown in Figure 6.

30 Following implantation of ring 100 into the tissue annulus 42, inner orifice ring 12 as shown in Figure 1 is coupled to ring 100 as described with respect to Figures 1-5.

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Figure 9 is a perspective view of implantation tool 150 for use in implanting orifice ring 100. Tool 150 includes legs 152 having coupling tips 154 which are configured to couple to ring 100. Tool 150 may be used
5 by the surgeon to hold ring 100 during suturing such that force may be applied to ring 100. Tips 154 may be fit into suturing grooves 108. Tool 150 includes handle attachment opening 156 which may be used to selectively engage an elongated handle (not shown). Opening 156 can
10 be as shown or can be a threaded hole, a snap fit hole or other opening adapted to selectively engage an elongated handle.

In FIG. 10, driver tool 210 is shown engaging outer ring 212 of a two piece prosthetic heart valve.
15 Driver tool 210 couples to helical screw fasteners 214 which pass through holes in outer ring 212. Helical fasteners 214 can be any fastener that advances along its central axis by being turned about that axis, i.e., anything that goes in by twisting, such as a screw.
20 Helical screw fasteners 214 attach outer ring 212 to tissue annulus 213 during an implantation procedure using driver tool 210. Driver tool 210 includes tool housing 216, which is generally cylindrical in shape, or round in cross section, and extends from distal end 218,
25 which engages outer ring 212, to proximal end 220 spaced away from the distal end 218. Drive shaft 222 at proximal end 220 has a handle 224 that can receive a twisting or driving force for transmission to helical screw fasteners 214. Handle 224 can also be actuated or
30 pulled away from the proximal end 220 to disengage driver tool 210 from helical screw fasteners 214.

In FIG. 10, handles 226, 228 project laterally from proximal end 220. Handles 226, 228 can be manually

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squeezed together to retract or disengage driver tool 210 from outer ring 212. When handles 226, 228 are squeezed together, tool housing 216 slides relative to tube 232. Handles 226, 228 pivot on pin 227. Handle 226 is rigidly coupled to tube 232. Handle 228 has slot 229 engaging a pin in tool housing 216. When handles 226, 228 are squeezed together, tool housing 216 moves toward outer ring 212 while other parts of drive tool 210 remain stationary relative to handle 226. Tool housing 216 pushes outer ring 212 away from tool 210, releasing outer ring 212 from tool 210 when handles 226, 228 are squeezed together. Spring 225 maintains handles 226 and 228 in the open or spread apart position and prevents accidental dislodgement of ring 212.

As an alternative to the handles 226, 228 of FIG. 10, a release button, along with additional springs can be disposed on the proximal end of tool 210. With this alternative, when the installation of helical fasteners 214 is complete, the release button can be pressed, releasing a catch to retract driver tool 210 from outer ring 212.

In FIG. 11, another alternative embodiment of a tool 211 is shown where there are no handles 226 and 228 as in FIG. 10, and spring 225 prevents accidental dislodgement of ring 212 while the health professional grasps tool housing 216. In FIG. 11, components which are similar to those in FIG. 10 are identified with the same reference numerals used in connection with the description of FIG. 10.

In FIG. 11, after helical screw fasteners 214 are driven in by tool 211 in the same manner that helical screw fasteners 214 are driven in by tool 210 (FIG. 10), the handle 224 is lifted or pulled up

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relative to tool housing 216 while the surgeon holds tool housing 216. This lifting action first lifts drive shaft 222, compresses spring 272, thereby disengaging helical screw fasteners 214 from the flexible shafts 262 (FIG. 12) of the tool 211. When spring 272 is fully compressed, lifting force is transferred through the compressed spring 272 to tube 232. When the handle is lifted further, tube 232 lifts relative to tool housing 216, compressing spring 225 while tube 232 remains in contact with outer ring 212. Spring 225 is made stiffer than spring 272 so that the flexible shafts 262 (FIG. 12) disengage from the helical screw fasteners 214 before the tube 232 lifts to release outer ring 212 from tool 211. Tool housing 216 moves toward outer ring 212 while other parts of driver tool 211 retract or move away from outer ring 212. The tool 211 is thus fully disengaged from outer ring 212 and helical screw fasteners 214 after use.

In FIG. 12, distal end 218 is shown in more detail. At distal end 218, cylindrical end 234 of tool housing 216 abuts outer ring 212. Struts 236 of tube 232 extend beyond cylindrical end 234 to engage outer ring 212 with a snap fit between groove 238 of struts 236 and locking ridge 240 of outer ring 212. Outer ring 212 is thus retained securely on distal end 218. Helical screw fasteners 214 pass through holes 242 in outer ring 212 and into tissue annulus 213. In one embodiment, there are approximately eight to sixteen helical fasteners although any number can be used, each passing through a separate hole 242 in outer ring 212. Helical screw fasteners 214 can be formed of metal wire compatible with implantation, and have a hub portion 244 which is wound in a polygonal shape, typically a

-13-

hexagon, and the remainder 246 of the helical fastener is wound in a helix with a sharp point 247 at the end. In another embodiment, the last coil of the hub portion 244 turns into the center of the coil (as described
5 later in FIGS. 18-19).

In FIG. 12, drive shaft 222 couples to drive train 250. Drive shaft 222 may be narrowed to form a gear shaft 252 on its end. Gear plate 254 is assembled on gear shaft 252 so that gear shaft 252 is free to spin. Gear 256 is attached to gear shaft 252 so that
10 gear shaft 252 drives gear 256. Satellite gears 258 are assembled on plate 254 with gear hubs 259 extending through holes in plate 254 so that they engage or mesh with gear 256. Plate 261 is also assembled onto gear
15 shaft 252 with gear hubs 257 extending through holes in plate 261 so that gear shaft 252 is free to spin. Retaining ring 260 is then attached to gear shaft 252 to keep gears 256 and satellite gears 258 caged between gear plates 254, 261. Gear plates 254 and 261 are
20 provided with multiple tabs 263 which are shaped to mate with slots 265. This arrangement prevents drive train 250 from rotating within tube 232 when drive shaft 222 is rotated. Satellite gears 258 are coupled to flexible shafts 262 which extend to helical screw fasteners 214.
25 There are multiple satellite gears 258 and multiple flexible shafts 262, however, for clarity only two of each are illustrated in FIG. 12. In one embodiment, if a second gear 256 is provided to drive some of the fasteners. For example, eight shafts 262 could be
30 driven by gear 256 and a second gear (not shown) located above gear 256 could drive eight more shafts 262 which extend vertically through the spaces shown in Figure 14. Flexible shafts 262 pass through holes in plate 264 and

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in housing 270. Plate 264 and housing 270 are fixed relative to tube 232 and retain flexible shafts 262 in a favorable orientation to transmit twisting motion from the vertical axis of drive shaft 222 to the axis of each helical screw fastener 214. With the satellite gears 258 held in relatively fixed locations relative to tube 232, when drive shaft 222 is twisted relative to tube 232, gear 256 drives satellite gears 258 so that they distribute twisting motion to all eight, or more, flexible shafts 262 simultaneously. Flexible shafts 262, in turn, couple this twist or drive to the helical screw fasteners 214 (only two are shown in FIG. 12). Driver tips 266 on the ends of flexible shafts 262 are shaped to engage the hub portions 244 of helical screw fasteners 214. Typically, driver tips 266 have a hexagonal, square or cylindrical slotted shape and slidably engage a correspondingly hexagonal or square or cylindrical slotted hub shape of helical screw fasteners 214 to transmit torque. Torsional drive is thus distributed from drive shaft 222 (or handle 224) through drive train 250 to drive helical screw fasteners 214 into tissue annulus 213. Helical screw fasteners 214 advance at approximately right angles to the hand twisting motion and at approximately right angles to tool housing 216. Driver tool 210 is inserted in a convenient straight direction down the aorta toward the tissue annulus 213, avoiding having to approach individual helical screw fasteners 214 at awkward or difficult angles and at different radial directions. All of helical screw fasteners 214 advance simultaneously, avoiding delay in completing the implantation.

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In FIG. 12, cylindrical housing 270 is snap fit in tube 232 and serves as a guide for flexible shafts 262, which reduces binding or tangling of flexible shafts 262. Compression spring 272 presses
5 drive train 250 toward distal end 218 to keep driver tips 266 engaged with helical screw fasteners 214. Handle 224 (FIG. 10) can be pulled away from tool housing 216, compressing spring 272 and moving drive train 250 away from distal end 218. When drive train
10 250 is moved away from distal end 218, driver tips 266 are slid out of or decoupled from helical screw fasteners 214.

In FIG. 13, an enlarged end view of distal end 218 is shown. In FIG. 13, outer ring 212 has been
15 omitted from the drawing for clarity. End 234 of tool housing 216 is generally cylindrical in shape and houses tube 232 which, in one embodiment, has four struts 236 extending from it. Flexible shafts 262 pass through holes 271 in cylindrical housing 270 and couple with hub
20 portions 244 of helical screw fasteners 214. Helical screw fasteners 214 have a helical portion 246 for engaging tissue. Helical portion 246 also couples with the holes 242 in outer ring 212 (FIG. 12) such that helical screw fasteners 214 are self-advancing when
25 twisted about their central axis. Hub portion 244 of helical screw fasteners 214 slides along driver tips 266 to accommodate the advancing motion. This arrangement keeps the helical screw fasteners 214 retained to the tool 210, preventing the fasteners from becoming
30 prematurely detached from the tool. In one embodiment, shafts 262 extend directly in a radial direction or bend to go to a drive tip 266 at a different location due to space limitation in housing 270. In FIGS. 10-13 all of

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the helical screw fasteners 214 can be advanced simultaneously into tissue when handle 224 is twisted relative to tool housing 216. Each flexible shaft 262 turns or bends in a different radial direction.

5 In FIG. 14, internal construction of drive train 250 is shown. FIG. 14 is a sectional view along line 14-14 of FIG. 12. In this embodiment, gear 256 is shown attached to gear shaft 252 and engaging all (e.g. eight or more) satellite gears 258. Gears 256, 258 are
10 spur gears which mesh with each other as shown only partially at 274. The satellite gears are attached to flexible shafts 262 which serve as axles for the satellite gears 258. Drive train 250 is housed within tube 232 which, in turn, is housed in tool housing 216.
15 The use of flexible shafts permits coupling around sharp, approximately right angle turns with multiple radial directions of drive for the multiple helical fasteners.

The tissue annulus of the heart has been
20 prepared to receive the heart valve prosthesis pursuant to techniques known in the art. Driver tool 210 has been preloaded with outer ring 212 snapped on its distal end 218 and helical screw fasteners 214 inserted in outer ring 212 and coupled to driver tips 266. Distal
25 end 218 is then advanced toward prepared tissue annulus 213 until outer ring 212 is aligned within the tissue annulus. Handle 224 is twisted to advance helical screw fasteners 214 into the tissue annulus. When outer ring 212 is attached by helical screw fasteners 214 to the
30 tissue annulus, handle 224 is lifted relative to tool housing 216. This compresses spring 272 and disengages driver tips 266 from helical screw fasteners 214 if they have not already been disengaged by the advance of the

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helical fasteners. Handles 226 and 228 are squeezed together, unsnapping outer ring 212 of the heart valve from the tool 210. The tool 210 is removed, leaving outer ring 212 attached to the tissue annulus of the heart by multiple helical fasteners.

In FIGS. 15 and 16, an alternative embodiment 300 of the distal end of the driver tool shown in FIGS. 10 and 11 is shown. In Figure 15, drive shaft 322, corresponding to drive shaft 222 in FIGS. 10 and 11, has a tapered portion 302 and a splined tip 304 at the distal end. The splined tip 304 engages a central hub 306 of a turntable 308 for rotating the turntable 308. Turntable 308 has a circular gear rack 310 spaced radially outward from the central hub 306. A plurality of spur gears 312 engage the circular gear rack 310 with loose tolerances, allowing for any misalignment between the spur gears 312 and the turntable. Each spur gear 312 has a hub 314 surrounding a throughhole 316 along a central axis of spur gear 312. Each hub 314 is flared or swaged outwardly to secure it to mounting tube 318 such that it is free to spin when driven by circular gear rack 310. Turntable 308 is free to spin in a circular groove 309 formed on the end of mounting tube 318. Each throughhole 316 is shaped to receive and loosely engage a driver tip 324. When driver tips 324 are hexagonal, then throughhole 316 has a corresponding hexagonal shape and is slightly larger than driver tip 324. A spring arrangement 326 coupled to the plurality of driver tips 324 provides axial force to the driver tips 324 for driving helical fasteners 214. Turntable 308 and spur gears 312 comprise a drive train for driving the driver tips 324. Spring arrangement 326 comprises a plurality of springs 330 which can be formed

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from flat strips of spring steel or other suitable material. Each spring 330 is attached to mounting tube 318 with a fastener 339. Each spring is also attached to a driver tip 324 with a fastener 335 so that driver
5 tip 324 rotates easily on fastener 335 when it is driven by spur gear 312. Each spring 330 engages tapered portion 302 at contact point 332. When drive shaft 322 is down (as illustrated in FIG. 15) the spring arrangement 326 applies a radially outward force to the
10 driver tips assisting with engagement of tissue 334. When drive shaft 322 is lifted up, the contact points 332 engage a narrower cross-section 333 of the tapered portion 302, resulting in a radially inward retraction force on the driver tips 324. Also, when drive shaft
15 322 is lifted, the turntable 308 disengages from spline 304, allowing the turntable 308 to rotate easily, which facilitates disengagement of driver tips 324. Drive shaft 322 is held in a position for driving by coil spring 336, which is compressed between lip 337 on
20 driveshaft 322 and tube 232. When drive shaft 322 is lifted, spring 336 is compressed first to provide disengagement, and then as drive shaft 322 is lifted further, fully compressed spring 336 transfers lifting force to tube 232, and secondly then, spring 225, which
25 is stiffer than spring 336, is compressed to allow disengagement of struts 236 from protruding ring 240 of outer ring 212.

In the embodiments shown in FIG. 15, the springs 330 can be assisted by additional coil springs
30 secured at location 331, if desired.

In FIG. 17, a further embodiment 350 is shown which is similar to the embodiment shown in FIGS. 15-16, except that the gears 352 are beveled gears and the

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circular gear rack 354 is correspondingly beveled to engage the beveled gears 352. Parts in FIG. 17 which are similar to those in FIGS. 15-16 have the same reference numbers that are used in FIGS. 15-16.

5 In the embodiments shown in FIG. 17, the springs 330 can be assisted by additional coil springs secured at location 331, if desired.

In FIG. 18, a further preferred embodiment of a helical screw fastener 400 is shown, and a
10 corresponding driver tip 402 is shown in FIG. 19. Helical screw fastener 400 has a hub 404 which includes a last coil which turns into the center of helical screw fastener 400 to form a drive lug 406 which can receive a torsional force. Helical screw fastener 400 has a
15 helical main body 408 ending in a sharp point 410 for engaging a tissue annulus such as tissue annulus 213 of FIG. 12. The driver tip 402 of FIG. 19 includes a slot 420 with a slot base 422 for slidably engaging drive lug 406. The driver tip 402 includes a round shaft 424
20 which slidably engages the main body 408 of helical screw fastener 400. The driver tip 402 also includes a shoulder 426 which, along with the slot base 422 provides an axial driving force to helical screw fastener 400, urging the sharp point 410 toward the
25 tissue annulus 213 of FIG. 12. Preferably, helical screws 214 may be coupled with outer ring 212 such that they are self advancing, thereby needing no axial driving force and simply advance into tissue annulus 213 as they are turned. Helical screw fastener 400 and
30 driver tip 402 can be used in the tools shown in FIGS. 10-17.

For convenience, a driver tool 210 as shown in any of FIGS. 10-17, outer ring 212 and multiple helical

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screw fasteners 214 are provided assembled in a package as a sterilized kit. The tool is preloaded by having outer ring 212 snapped in place on the distal end, helical fasteners preloaded in holes in the outer ring and the driver tips coupled to the helical fasteners.

Preferably, the rings set forth herein are formed of biocompatible materials. The outer ring is generally made of material more flexible than the inner ring, such as polyethylene terephthalate (PET), polyetheretherketones (PEEK), ultrahigh molecular weight polyethylene, Nitinol® (a nickel-titanium alloy), and polyurethane. The inner ring is made preferably of a material more rigid than the outer ring such as titanium, MP35N (wrought cobalt-nickel-chromium-molybdenum alloy), ceramic, Elgiloy® (cobalt-chromium-nickel-molybdenum iron alloy), pyrolytic carbon or other rigid polymers for the inner ring. The particular shapes of the orifice rings and attachment mechanisms may be modified as appropriate. The ring coupling mechanism for coupling the two rings may be any mechanism as desired and is not limited to the particular "snap" coupling techniques set forth herein. For example, the coupling techniques may include screws, wires, bayonet locking mechanism, and nails which extend axially and engage the rings. Further, the configuration of the inner orifice ring and its occluding mechanism may be other than those set forth herein.

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Implantation time is short and relatively simple implantation techniques can be used. Further, the angular positioning of the leaflets in the inner ring is easily accomplished by rotating the inner ring with respect to the outer ring. The invention allows surgical access to subvalvular features prior to coupling the inner ring to the outer ring without the possibility of damaging the occluding mechanism, for example. The inner valve ring can be removed and replaced without excising the entire prosthesis. The complexity of surgery is reduced because manual suturing may not be required. The area of the lumen is increased over typical prior art designs and a lower profile results because the cuff attachment mechanism requires less area. With the inner ring coupled to the outer ring, the outer ring attachment mechanisms are prevented from "backing out" and completely shielded from blood flow where they could otherwise initiate formation of thrombus. Any type of occluding mechanism may be used and the attachment mechanism may be integral with the ring body. The invention also eliminates suturing such that the implantation procedure is faster. Further, there are no suture tails which could lead to thrombus formation. The invention is also useful in minimally invasive surgery because the attachment is with a single elongate tool which can be placed through a trocar in the patient and the entire valve attached in a single step.

The component parts of tools depicted in FIGS. 10-17 can be constructed of biocompatible polymers such as polyurethane, delrin, polysulfone, of metals such as stainless steel, or of other biocompatible materials. Gears are preferably constructed of nylon, teflon or

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stainless steel. The completed tool or kit can be gamma sterilized and disposable, if desired. Flexible shafts can be formed of stainless steel and coated with nylon or teflon for lubricity. Helical screw fasteners can be
5 made of platinum-iridium alloy, MP35N (a wrought cobalt-nickel-chromium-molybdenum alloy), stainless steel, titanium or other biocompatible materials. If desired, an electric motor can be used to provide the torsional force rather than manually twisting a handle.

10 Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

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WHAT IS CLAIMED IS:

1. A driver tool for a heart valve prosthesis component for driving helical fasteners through the heart valve prosthesis component into a tissue annulus
5 of the heart, comprising:
 - a tool housing having a distal end couplable to engage the heart valve prosthesis component and a proximal end spaced away from the distal end; and
 - 10 a drive train mounted in the tool housing having a drive shaft at the proximal end couplable to a driving force and a plurality of driver tips at the distal end couplable to the helical fasteners
15 in the heart valve prosthesis component, the drive train distributing the driving force to each of the driver tips.
2. The driver tool of claim 1, further comprising:
 - 20 a first handle extending from the proximal end and manually actuatable to couple a first actuation motion; and
 - a disengagement mechanism in the tool housing receiving the first actuation motion and
25 disengaging the driver tips from the helical fasteners responsive to the first actuation motion.
3. The driver tool of claim 2, further comprising:
 - 30 a second handle extending from the proximal end and manually actuatable to couple a second actuation motion; and

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5 a decoupling mechanism in the tool housing
 receiving the second actuation motion
 and decoupling the driver tool from the
 heart valve prosthesis component
 responsive to the second actuation
 motion.

4. The driver tool of claim 1, wherein the drive
train further comprises flexible shafts coupling the
driving force to the driver tips.

10 5. The driver tool of claim 4, wherein the
flexible shafts make a turn to engage the driver tips.

6. The driver tool of claim 5, wherein the
flexible shafts make turns in a different radial
direction for each flexible shaft.

15 7. The driver tool of claim 1 wherein the drive
train further comprises:

 a turntable with a central hub coupled to the
 drive shaft and a circular gear rack
 spaced radially outward from the central
20 hub;

 a plurality of gears engaging the circular gear
 rack, each gear having engaging a driver
 tip.

8. The driver tool of claim 7 further comprising:
25 a spring arrangement coupled to the plurality of
 driver tips to provide axial force to
 the driver tips.

9. The driver tool of claim 8 wherein the drive
shaft has a tapered surface coupled to the spring
30 arrangement controlling the axial force to the driver
tips.

10. The driver tool of claim 7 wherein the
plurality of gears are beveled.

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11. The driver tool of claim 1 wherein the helical fasteners are self-advancing.

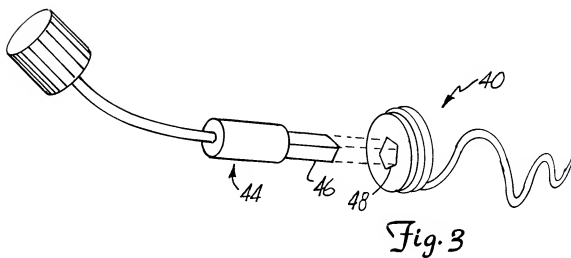
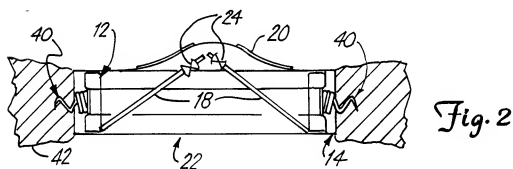
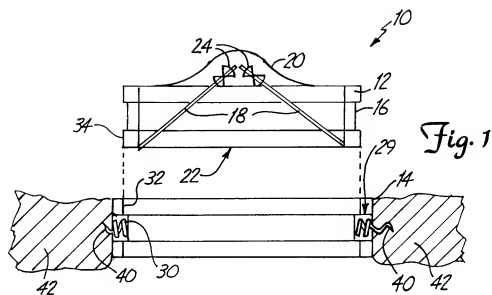
12. The driver tool of claim 1 wherein the drive train comprises a central gear coupled to the drive shaft and
5 a plurality of satellite gears engaging the central gear and coupled to the driver tips.

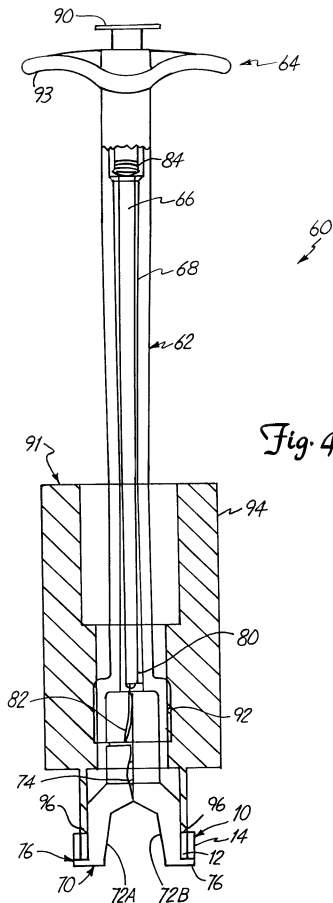
13. A driver tool for driving helical fasteners through a heart valve component into tissue, comprising:
a tool housing having a distal end couplable
10 to engage the heart valve component and a proximal end spaced away from the distal end;
a drive shaft extending from the proximal end, the drive shaft being twistable by
15 a twisting force;
a plurality of driver tips extending from the distal end, each driver tip couplable to a helical fastener for the heart valve component; and
20 a drive shaft coupled to a drive handle and extending into the tool housing;
a drive train in the tool housing coupling the twisting from the drive shaft to the driver tips.

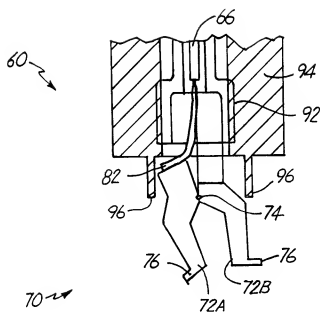
25 14. A method of attaching an outer ring of a heart valve prosthesis component into a tissue annulus of a heart with helical fasteners, comprising:
providing a driver tool which has a handle
extending from a drive shaft on a
30 proximal end for distributing drive to multiple driver tips on a distal end;
attaching the outer ring of the heart valve prosthesis component to the distal end;

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- placing the multiple helical fasteners on the multiple driver tips and passing them through the outer ring of the heart valve prosthesis component;
- 5 placing the outer ring into the tissue annulus of the heart
- driving the multiple helical fasteners into the annulus of the heart by twisting the drive shaft; and
- 10 removing the driver tool from the outer ring, leaving the outer ring attached to the tissue annulus.
15. A kit for attaching a heart valve prosthesis component to an annulus of tissue in a heart,
- 15 comprising:
- an outer ring of a heart valve prosthesis component;
- a driver tool having a handle extending from a drive shaft on a proximal end and distributing drive to a plurality of driver tips on a distal end of the driver tool, the distal end being
- 20 removably attached to the outer ring of the heart valve prosthesis; and
- 25 a plurality of helical fasteners passing through the outer ring of the heart valve prosthesis, each one of the helical fasteners removably coupling to one of the plurality of driver tips.





*Fig. 5*

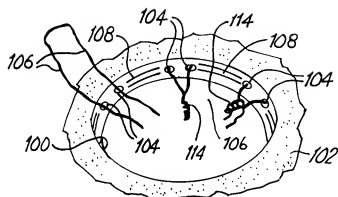


Fig. 6

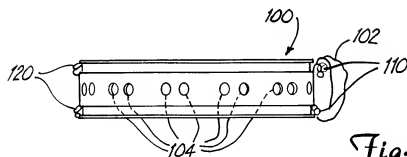


Fig. 7A

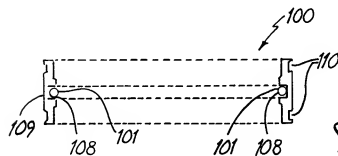


Fig. 7B

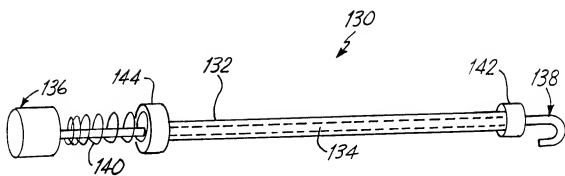


Fig. 8

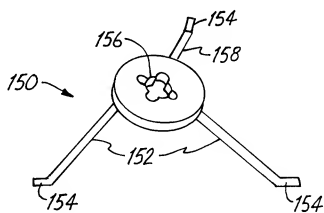
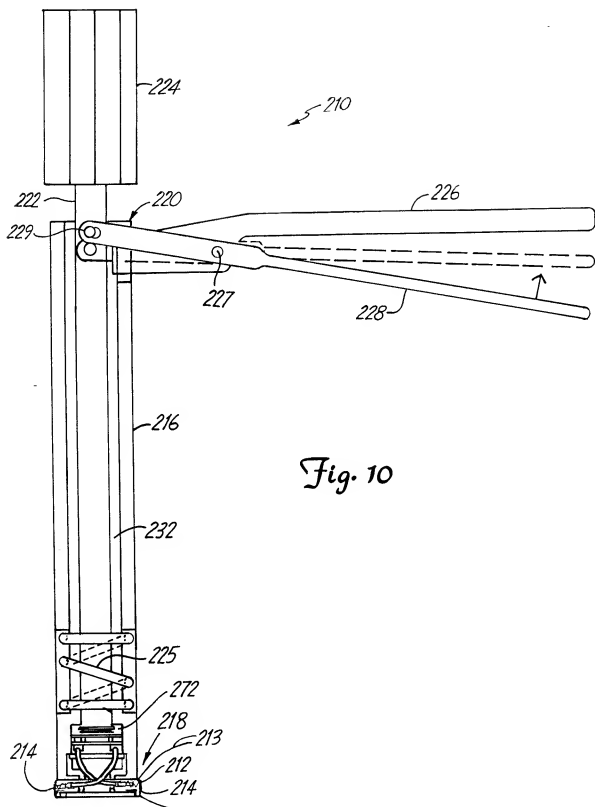
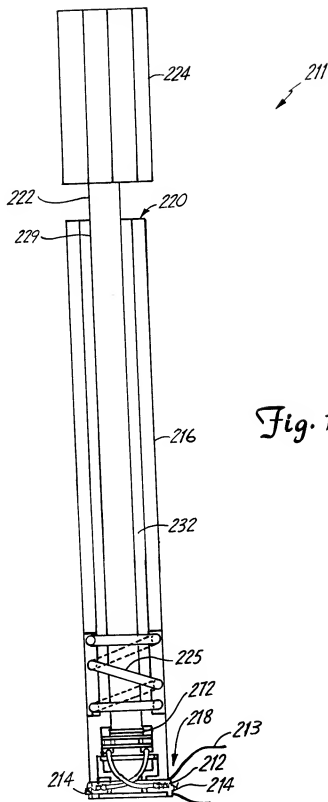


Fig. 9





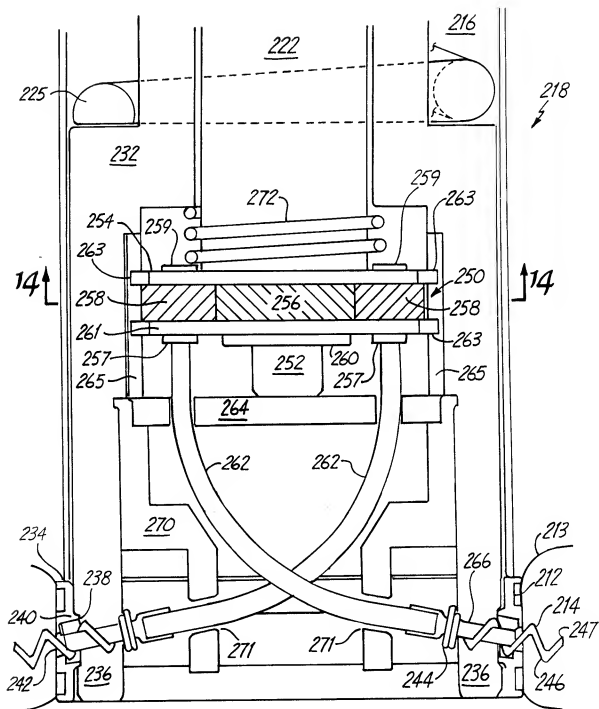


Fig. 12

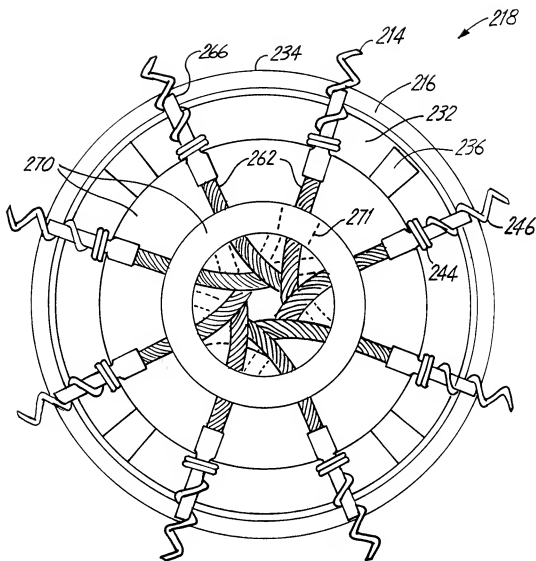
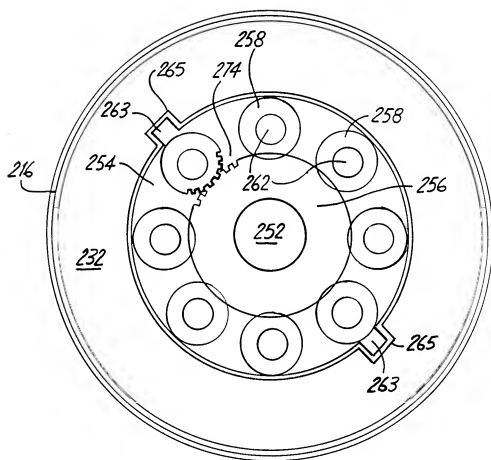


Fig. 13

*Fig. 14*

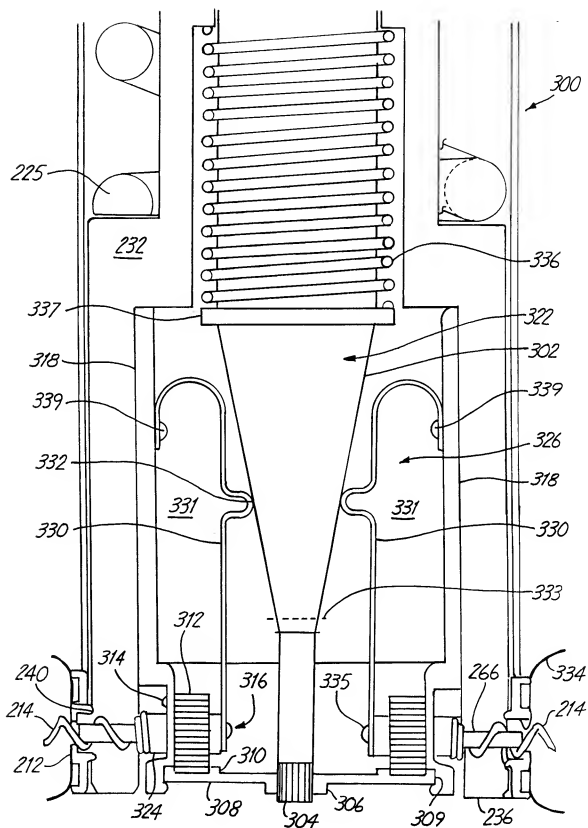
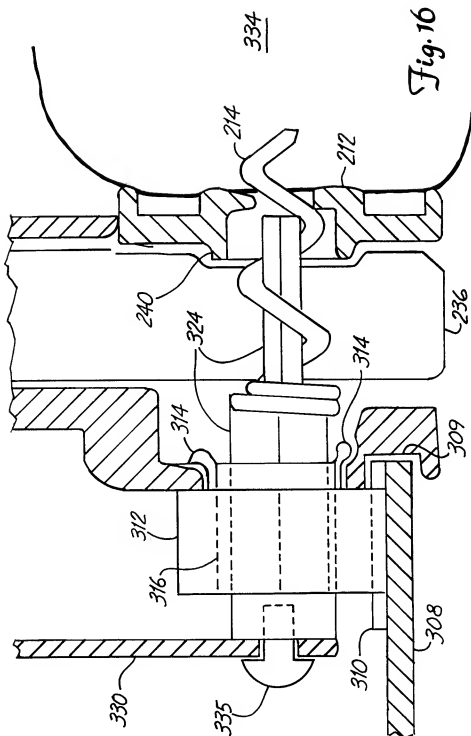


Fig. 15



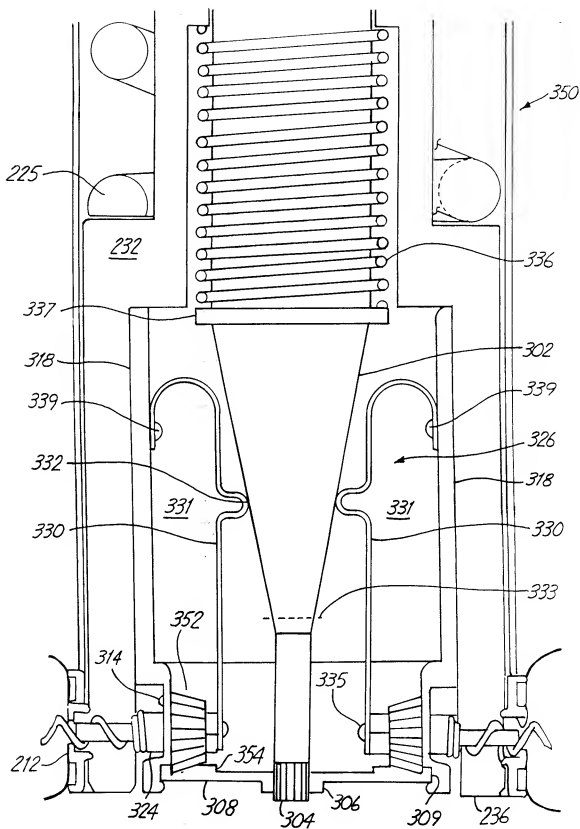
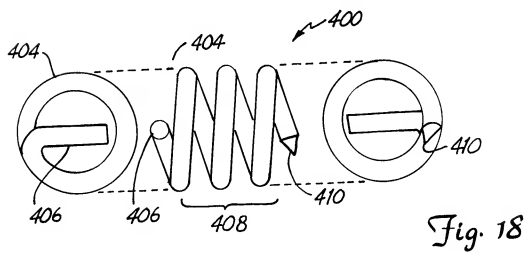
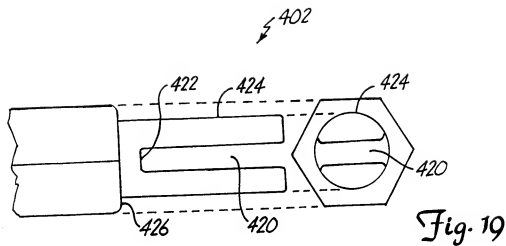


Fig. 17



A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61B17/064 A61B17/068 A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B A61F B23P

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 97 30659 A (WILLIAMSON ET AL.) 28 August 1997 (1997-08-28) abstract; figures ---	1, 13, 15
A	US 3 686 740 A (SHILEY) 29 August 1972 (1972-08-29) abstract; figures ---	1, 13, 15
A	FR 1 386 811 A (SURGITOOOL INCORPORATED) 14 May 1965 (1965-05-14) page 3, left-hand column, paragraph 2 - right-hand column, paragraph 1; figures ---	1, 13, 15
A	WO 97 09948 A (ST. JUDE MEDICAL, INC.) 20 March 1997 (1997-03-20) abstract; figures ---	1, 13, 15
	-/--	



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

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Date of the actual completion of the international search

13 August 1999

Date of mailing of the international search report

19/08/1999

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Giménez Burgos, R

INTERNATIONAL SEARCH REPORT

Intern 1st Application No

PCT/US 99/08817

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 96 03925 A (ORIGIN MEDSYSTEMS, INC.) 15 February 1996 (1996-02-15) claim 1; figures ----	1, 13, 15
A	EP 0 544 102 A (BRIDGESTONE CORPORATION) 2 June 1993 (1993-06-02) -----	

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 99/08817

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 14
because they relate to subject matter not required to be searched by this Authority, namely:
RULE 39.1(IV) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

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2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/08817

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9730659	A	28-08-1997	US 5716370 A AU 1956297 A CA 2245771 A EP 0883387 A US 5891160 A	10-02-1998 10-09-1997 28-08-1997 16-12-1998 06-04-1999
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EP 0544102	A	02-06-1993	JP 5146975 A US 5277085 A	15-06-1993 11-01-1994

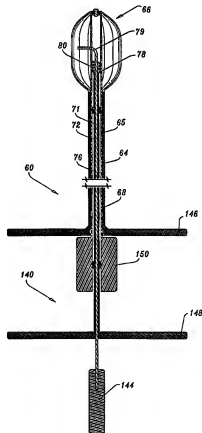
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 17/08	A1	(11) International Publication Number: WO 00/16701 (43) International Publication Date: 30 March 2000 (30.03.00)
<p>(21) International Application Number: PCT/US99/21414</p> <p>(22) International Filing Date: 17 September 1999 (17.09.99)</p> <p>(30) Priority Data: 60/101,050 18 September 1998 (18.09.98) US</p> <p>(71) Applicant (for all designated States except US): UNITED STATES SURGICAL CORPORATION [US/US]; 150 Glover Avenue, Norwalk, CT 06856 (US).</p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only): PARODI, Juan Carlos [AR/AR]; Blanco Encalada 1543/47, (1428) Capital Federal (AR). RATCLIFF, Keith [US/US]; 14 Concorde Ridge, Newtown, CT 06470 (US). RENDE, Frank, M. [US/US]; 58 George Street, Stamford, CT 06902 (US). SHERTS, Charles, R. [US/US]; 443 Riverside Avenue, Westport, CT 06880 (US).</p> <p>(74) Agents: BARRESE, Rocco, S. et al.; Dilworth & Barrese, 333 Earle Ovington Boulevard, Uniondale, NY 11553 (US).</p>		<p>(81) Designated States: CA, JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p>Published <i>With international search report.</i></p>

(54) Title: ENDOVASCULAR FASTENER APPLICATOR

(57) Abstract

An endo-vascular fastener applicator (50) is provided for endo-luminal fastening a prosthetic (100) to a vessel with a fastener (80). The applicator (50) includes a tubular body (64) that is configured for positioning within a vessel, an expandable portion (66) disposed adjacent distal end of the tubular body, and deployed to support a prosthetic (100) in contact with an inner surface of a vessel. A drive assembly (60) is included for advancing a fastener (80) into the prosthetic (100). The endo-vascular fastener applicator (50) may include a control assembly (140). A delivery tube (72) may be included that is disposed for movement within the tubular body, and which defines a channel for movement of the drive assembly there within. The delivery tube (72) may include an applicator head (73). The applicator head (73) may include an injection mount (80) that is disposed for movement relative to a prosthetic (100). An endo-vascular fastener applicator system (50) is disclosed for repairing a damaged portion of a vessel. A method for endo-luminal repairing a damaged portion of a vessel is disclosed.



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ENDOVASCULAR FASTENER APPLICATOR

CROSS-REFERENCE TO RELATED APPLICATIONS

This Patent Application claims the benefit of U.S. Provisional Application Serial No. 60/101,050 filed September 18, 1998, by Parodi et al., the entire contents of which are hereby incorporated by reference.

BACKGROUND

1. Technical Field

This disclosure relates generally to vascular grafts for intraluminal delivery, and in particular, to a method and apparatus for repairing diseased or damaged sections of a vessel by fastening a prosthesis within the vessel.

2. Description of Related Art

Diseased or damaged blood vessels often cause weakening of the vessel wall resulting in an aneurysm whereby a blood vessel and especially an artery have a section of abnormal blood-filled dilation. For example, an abdominal aortic aneurysm is a sac caused by an abnormal dilation of the wall of the aorta, a major artery of the body as it passes through the abdomen.

The abdominal aortic aneurysm usually arises in the infrarenal portion of the arteriosclerotically diseased aorta, for example, below the kidneys. Left untreated, the aneurysm will eventually cause rupture of the sac with ensuing fatal hemorrhaging in a very short time. High mortality associated with rupturing led the state of the art into trans-abdominal surgical repair of abdominal aortic aneurysms.

Surgery involving the abdominal wall, however, is a major undertaking with

associated high risks. This type of surgery, in essence, involves replacing the diseased and aneurysmal segment of blood vessel with a prosthetic device which typically is a synthetic tube, or graft, usually fabricated of either DACRON™, TEFLON™, or other suitable material.

5 The present state of the art for intraluminal repair of a vessel does not fasten a prosthesis to the remaining aortic wall. For example, U.S. Patent Nos. 5,571,171 and 5,571,173 disclose a method and apparatus for treating an abdominal aortic aneurysm by supplying a prosthesis or an aortic graft for intraluminal delivery that does not fasten the graft to the remaining aortic wall.

10 Presenting an aortic graft through the aorta by intraluminal delivery avoids major invasive surgery. The '171 and '173 patents disclose an aortic graft that is delivered intraluminally to the aneurysm site. The aortic graft is secured to the remaining aortic wall by a balloon that is inflated thereby causing the graft to contact and adhere to the remaining aortic wall.

15 The major disadvantages related to the combination of endovascular expanders, such as a balloon or stent, and prosthesis is the dilation of the natural artery with consequent migrations and periprosthetic losses. Upon withdrawal of the expander, the tissue is caused to collapse and the prosthesis disengages from the remaining aortic wall and tends to migrate to a location away from the aneurysm site to be repaired. The migration and movement of the disengaged aortic graft would then obstruct the affected vessel. The migration and movement of the aortic graft requires further treatment on the patient to remove the failed attempt to attach the aortic graft to the remaining aortic wall.

20 Further treatment may include major surgery that is hazardous and traumatic to the patient. Major surgery to remove the aortic graft defeats the benefits of intraluminal delivery of the aortic graft. The current state of the art does not disclose a fastener applicator that intraluminally delivers a vascular graft and endoluminally applies internal fasteners to fasten a prosthesis in place.

25 Accordingly, there is a present need for a fastener applicator that intraluminally

delivers a vascular graft to a site within a vessel and applies fasteners to pass through both a prosthesis and the thickness of a vessel wall. The fastened prosthesis should also have the capability of following dilation of a vessel.

5

SUMMARY

An endovascular fastener applicator for endoluminally delivering prostheses for treating a vessel is disclosed. The endovascular fastener applicator includes a delivery assembly and a control assembly. The delivery assembly delivers a graft to a site within a vessel and fastens the prosthesis to a vessel by passing a fastener therethrough. The delivery assembly may include an outer sleeve, delivery tube and drive assembly for fastening a prosthesis to a vessel. The control assembly controls operation of the graft delivery catheter. At least a portion of the applicator can be fabricated from a shape memory material. The applicator can be configured to deploy multiple fasteners.

In one embodiment, an endovascular fastener applicator is provided for endoluminally fastening a prosthetic to a vessel with a fastener, in accordance with the present disclosure. The applicator includes a tubular body that is configured for positioning within a vessel. An expandable portion is disposed adjacent a distal end of the tubular body and is deployable to support a prosthetic in contact with an inner surface of a vessel. A drive assembly is also included for advancing a fastener into the prosthetic. The drive assembly can be coaxially disposed within the tubular body. The drive assembly may include a curved portion oriented at an angle of substantially 90° from a longitudinal axis defined by the tubular body. In an alternate embodiment, the drive assembly includes a drive rod having a rectangular cross-section. The drive rod cooperates with an inner diameter of a fastener whereby movement of the drive rod causes advancement of a fastener. The drive assembly may be configured for axial and rotational motion.

25

The endovascular fastener applicator may include a control assembly that is

operatively connected to the drive assembly for extracorporeal control of the applicator. In one embodiment, the control assembly includes a handle having a pistol-grip trigger configuration.

5 The endovascular fastener applicator may include a delivery tube that is disposed for movement within the tubular body and which defines a channel for movement of the drive assembly therewithin. The delivery tube is configured for advancing a fastener within the tubular body. The delivery tube can be coaxially disposed with the tubular body. In another embodiment, the delivery tube includes an applicator head configured to facilitate deployment of the fastener. The applicator head may have a substantially
10 perpendicular orientation to a longitudinal axis defined by the delivery tube.

The fastener applicator may also include an elongate control positioned for movement within the tubular body. The expandable portion is operatively connected to a distal end of the tubular body and a distal end of the elongate control. The tubular body and the elongate control are manipulable to facilitate support of the prosthetic in contact
15 with an inner surface of a vessel. The elongate control can be coaxially disposed with the tubular body.

The expandable portion may include support members that define open interstitial regions therebetween. The support members can comprise a plurality of flexible wires. The support members may alternatively comprise a plurality of flexible tapes.

20 In one embodiment, the drive assembly may include at least one fastener guide configured to guide advancement of a fastener. Each fastener guide cooperates with a prosthetic for guiding advancement.

In another alternate embodiment, the applicator head includes an ejection mount that is disposed for movement relative to a prosthetic and configured for deployment of a plurality of helical fasteners. The ejection mount has an ejection head with a saw toothed
25 face which is configured for engaging a prosthetic. A ratchet assembly may be included that is configured to facilitate movement of the ejection mount.

In yet another alternate embodiment, an endovascular fastener applicator system

is disclosed for repairing a damaged portion of a vessel. The system includes at least one helical fastener and a prosthetic. Each helical fastener having a penetrating end and a limiting end. An endovascular fastener applicator, as discussed above, is also included. An applicator head, as discussed above, may be included, that is configured for engaging an interior portion of the prosthetic to facilitate uniform deployment of each helical fastener. A drive rod may have a cross-section corresponding to an interior cross-section defined by each helical fastener, and in cooperation, facilitate advancement and deployment of each helical fastener.

In an alternate embodiment, the prosthetic includes an interior band having anchor pads circumferentially spaced about and implanted within the band. The pads correspond to the open interstitial regions of the expandable portion. The drive assembly includes guide wires configured for guiding advancement of each helical fastener and have anchor legs adjacent a distal end of each of the guide wires. The anchor legs releasably engage the anchor pads prior to deployment of each helical fastener and are retractable from the prosthetic upon deployment of each helical fastener.

The applicator head may include an ejection mount configured for deploying at least one helical fastener and movable relative to an interior circumference of the prosthetic for deploying each helical fastener. The ejection mount includes an ejection head having a saw-toothed face for engaging the internal circumference of the prosthetic. The ejection head facilitates uniform deployment of each helical fastener.

A method for endoluminally repairing a damaged portion of a vessel is disclosed.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments are described herein with reference to the drawings, wherein:

FIG. 1 is a perspective view of one embodiment of an endovascular fastener applicator in accordance with the present disclosure;

FIG. 2 is a cross-sectional view, in part elevation, of an aortic graft placed at the site of an abdominal aortic aneurysm within the aorta;

FIG. 3 is an enlarged detail view of a portion of FIG. 2 illustrating the aortic graft secured to the remaining aortic wall and maintained in position by helical fasteners;

FIG. 4 is a cross-sectional view, in part elevation, of an aortic graft for treating an aortic aneurysm affecting the aorta and both iliac arteries;

FIG. 5 is a perspective view of a helical fastener;

FIG. 6 is a side elevation view of a helical fastener;

FIG. 7 is a bottom perspective view taken along line 7-7 of FIG. 6 of a helical fastener having a rectangular configuration at its limiting end for cooperating with a rectangular drive assembly;

FIG. 8 is a cross-sectional view taken along line 8-8 of FIG. 7 of a helical fastener;

FIG. 9 is a cross-sectional view, in part elevation, of an endovascular fastener applicator;

FIG. 10 is a cross-sectional view, in part elevation, of a distal portion of the applicator at the aneurysm site;

FIG. 11 is a cross-sectional view of the control assembly;

FIG. 12 is a cross-sectional view, in part elevation, of the applicator at the aneurysm site showing an expandable portion causing a prosthesis to contact a vessel wall;

FIG. 13 is a cross-sectional view of the control assembly;

FIG. 14 is a cross-sectional view, in part elevation, of the applicator at the aneurysm site showing advance of a delivery tube;

FIG. 15 is a cross-sectional view of the control assembly;

FIG. 16 is a cross-sectional view, in part elevation, of the applicator at the aneurysm site showing advance of a drive assembly;

FIG. 17 is a top view of a helical fastener defining a rectangular configuration at its limiting end for cooperating with a rectangular drive assembly, as shown in cross-section;

FIG. 18 is a cross-sectional view of the control assembly;

FIG. 19 is a cross-sectional view, in part elevation, of the delivery assembly showing rotation for insertion of a helical fastener;

FIG. 20 is a cross-sectional view, in part elevation, of an alternate embodiment of the applicator showing the delivery assembly at the aneurysm with fastener guides;

FIG. 21 is an enlarged detail view of a portion of FIG. 20 illustrating a helical fastener guided over a drive attached to a fastener guide;

FIG. 22 is a cross-sectional view, in part elevation, of a helical fastener taken along line 22-22 of FIG. 21;

FIG. 23 is a plan view, in part cross-section, taken along line 23-23 of FIG. 20 showing the applicator with fastener guides;

FIG. 24 is a perspective view of one embodiment of a fastener guide in accordance with the present disclosure;

FIG. 25 is a perspective view, in part cross-section, showing movement of the helical fastener over a drive prior to collapsing the fastener guide;

FIG. 26 is a perspective view, in part cross-section, showing the drive after the fastener guide is collapsed and the helical fastener deployed;

FIG. 27 is a perspective view, showing retraction of the drive and fastener guide;

FIG. 28 is a perspective view of an alternate embodiment of the control assembly;

FIG. 29 is a perspective view of the distal end of an alternate embodiment of the drive assembly loaded with a plurality of helical fasteners;

FIG. 30 is a perspective view showing a helical fastener for loading with a

channel of the drive assembly;

FIG. 31 is a perspective view of an alternate embodiment of a helical fastener;

FIG. 32 is a perspective view of an applicator head and helical fasteners prior to deployment into a prosthesis;

FIG. 33 is a perspective view of the helical fastener deployed into the prosthesis and artery;

FIG. 34 is a perspective view of an alternate embodiment of the applicator showing the expandable portion in an expanded state;

FIG. 35 is a perspective view of the expandable portion shown in FIG. 34 in a relaxed state;

FIG. 36 is an exploded view of the delivery assembly shown in FIG. 34;

FIG. 37 is an exploded view of the drive assembly shown in FIG. 34;

FIG. 38 is a perspective view of the drive assembly shown in FIG. 34;

FIG. 39 is a perspective view of an embodiment of an ejection mount ;

FIG. 40 is a perspective view of the ejection mount showing a set screw and cam divider for cooperating with the drive assembly;

FIG. 41 is a cross-sectional view of the applicator with the expandable portion in a relaxed state and a prosthetic having a sealing gasket;

FIG. 42 is a cross-sectional view, in part elevation, of the distal end of the applicator;

FIG. 43 is a cross-sectional view, in part elevation, with the expandable portion in an expanded state;

FIG. 44 is an enlarged cross-sectional view, in part elevation, of the distal end of the applicator;

FIG. 45 is a perspective view of the expandable portion in an expanded state and the ejection mount loaded with helical fasteners;

FIG. 46 is a cross-sectional view, in part elevation, with the ejection

mount pivoted for deployment of helical fasteners;

FIG. 46A is a perspective view, in part cross-section, an alternate embodiment of the ejection mount pivoted for deployment of helical fasteners;

FIG. 47 is a cross-sectional view, in part elevation, of the ejection mount engaging the aortic graft prior to deployment of helical fasteners;

FIG. 48 is a perspective view, in part cross-section, showing deployment of helical fasteners;

FIG. 49 is a perspective view, in part cross-section, showing retraction of the ejection mount;

FIG. 50 is a cross-sectional view, in part elevation, showing the ejection mount subsequent to deployment of a helical fastener; and

FIG. 51 is a top view of the applicator, showing movement of the ejection mount prior to deployment of a helical fastener.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

As illustrated in FIG. 1, the present disclosure relates to an endovascular fastener applicator, generally referred to as numeral 50. Endovascular fastener applicator 50 delivers aortic graft 100, as shown in FIGS. 2 and 3, for repairing an abdominal aortic aneurysm 120 in aorta 124 having two iliac arteries 126L and 126R associated therewith, as well as a plurality of renal arteries 130 located above aneurysm 120 in fluid communication with aorta 124. Repairing the aneurysm includes fastening an aortic graft 100 to an aortic wall 132 by fasteners 80. Aortic graft 100, as well as other prostheses, may be utilized in the thoracic aorta, and can be used to repair thoracic aneurysms or thoracic dissecting aneurysms. Further, the fastener applicator 50 may also treat vascular trauma and other obstructive diseases with various prostheses. Accordingly, use of the term aortic aneurysm in this specification and claims is intended to relate to and mean both abdominal aortic aneurysms, thoracic aneurysms and related vessel diseases.

Endovascular fastener applicator 50 has a delivery assembly 60 and a control assembly 140. Delivery assembly 60, as illustrated in FIG. 9, includes a tubular body, such as, for example, an outer sleeve 64, an elongate control 68, a delivery tube 72 and a drive assembly 76, each having a proximal and distal end relative to control assembly 140. Outer sleeve 64 defines a channel 65 and is adapted for insertion within aorta 124 (as shown in FIG. 10) and has an expandable portion 66 operatively connected at its distal end. Elongate control 68 is coaxially positioned within channel 65 of outer sleeve 64 and is operatively connected to expandable portion 66 at its distal end. Delivery tube 72 defines a channel 71 and is coaxially positioned within channel 65 of outer sleeve 64 and adapted for advancing a helical fastener 80 to the abdominal aortic aneurysm site. Drive assembly 76 is coaxially positioned within channel 71 of delivery tube 72 and adapted for advancing, in cooperation with delivery tube 72, and deploying helical fastener 80 into aortic graft 100 and aorta wall 132. It is contemplated that the components of the delivery assembly may be alternately oriented relative to each other, such as, for example, bi-axial, offset, etc. It is further contemplated that the components of delivery assembly 60 are flexible and may be constructed from a shape memory material.

Operation of endovascular fastener applicator 50 is controlled by control assembly 140. As shown in FIGS. 1 and 9, control assembly 50 includes outer sleeve push bar 146, expandable portion control 150, delivery tube push bar 148 and handle 144. Outer sleeve push bar 146 is operatively connected to the proximal end of outer sleeve 64 for regulating movement of outer sleeve 64. Expandable portion control 150 is operatively connected to the proximal end of elongate control 68, which in turn is connected to expandable portion 66. Correspondingly, expandable portion control 150 controls the expansible force AA (shown in FIG. 12) exerted by expandable portion 66 for supporting aortic graft 100 in contact with aortic wall 132. Outer sleeve push bar 146 may also be adapted to influence expansible force AA.

Delivery tube push bar 148 is operatively connected to the proximal end of

delivery tube 72 for regulating movement of delivery tube 72. Handle 144 is operatively connected to the proximal end of drive assembly 76, for controlling axial and rotational movement of drive assembly 76, described in detail below.

As shown in FIG. 9, drive assembly 76 includes a drive 78. Drive 78 at its distal end has a curved portion 79 oriented at substantially 90° to the longitudinal axis of outer sleeve 64 and delivery tube 72 (similarly shown in FIGS. 10 and 12). It is contemplated that the curved portion may be positioned at various angular orientations. Drive assembly 76 transmits rotational motion from its proximal end to its distal end and through its curved portion 79 to facilitate deployment of helical fasteners 80 into the aortic graft 100 and aortic wall 132.

In one embodiment, as illustrated in FIGS. 5-8, helical fasteners 80 have a sharpened distal end 81 and a penetration limit end 82. Helical fastener 80 has an outer diameter 83 and an inner diameter 84. Outer diameter 84 facilitates penetration of sharpened distal end 81 into aortic graft 100 and aortic wall 132. The surface of inner diameter 84 cooperatively engages drive assembly 76 and delivery tube 72 at their distal ends to facilitate loading of helical fastener 80 into endovascular fastener applicator 50. Preferably, inner diameter 84 and penetration limit end 82 have a rectangular configuration for cooperative engagement with drive assembly 76, drive assembly 76 also having a rectangular configuration at its distal end. Although a helical fastener is disclosed it is contemplated that fastener 80 may have various configurations, such as, for example, cylindrical, triangular, etc. It is further contemplated that fasteners 80 are of the metallic fastener staple type and are preferably made from stainless steel but may be constructed from a polymeric material.

In the embodiment illustrated in FIG. 9, drive 78 is made from a shape memory alloy whereby drive 78 assumes the curved configuration of curved portion 79 upon exiting delivery tube 72. Delivery tube 72 may also include an applicator head 73 at its distal end having a curved orientation to facilitate deployment of helical fasteners 80, as shown in FIGS. 14, 16 and 19. Helical fasteners 80, as shown in FIG. 3, are deployed

into aortic graft 100 and aortic wall 132 for fastening.

In an alternate embodiment, repair of abdominal aortic aneurysm 120, as shown in FIG. 10, proceeds by insertion of endovascular fastener applicator 50 into aorta 124 and advancing to the abdominal aortic aneurysm site by manipulation by a surgeon of control assembly 140. Endovascular fastener applicator 50 delivers aortic graft 100 to abdominal aortic aneurysm 120 by advancing the aortic graft 100 so that a sufficient portion of aortic graft 100 is brought in contact with aortic wall 132. Aortic graft 100 is a conventional tubular graft made of DACRON®, TEFLON® (polytetrafluoroethylene) and the like and is of a length sufficient to span the abdominal aortic aneurysm 120.

With reference to FIGS. 11-19, delivery assembly 60 and aortic graft 100 are delivered to the abdominal aneurysm site by manipulation of outer sleeve push bar 146, as shown by arrows A in FIG. 11. Aortic graft 100 is positioned at the abdominal aneurysm site. Expandable portion 66 is caused to expand, shown by arrows AA in FIG. 12, in response to cooperative manipulation of outer sleeve push bar 146 and elongate control 68. Outward radial force AA supports aortic graft 100 in contact with aortic wall 132. Expandable portion 66 facilitates fastening of aortic graft 100 with aortic wall 132 by deployment of helical fasteners 80. In this embodiment, expandable portion 66 includes support members 67 that define interstitial regions 70 therebetween. Helical fasteners 80 are deployed through interstitial regions 70 and into aortic graft 100. It is contemplated that helical fasteners 80 may be deployed at various locations about the circumference of aortic graft 100 relative to the number of support members 67 and spacing of interstitial regions 70.

Delivery tube push bar 148 is manipulated to axially advance delivery tube 72 within outer sleeve 64, as shown by arrows B in FIG. 13. At its distal end, delivery tube 72 has an applicator head 73 configured to have a substantially perpendicular orientation to the longitudinal axis of delivery tube 72. Drive 78 follows the substantially perpendicular orientation of delivery tube 72 to facilitate deployment of helical fasteners 80. It is contemplated that applicator head 73 may have various configurations and

orientations to facilitate deployment of helical fasteners 80.

With reference to FIG. 14, delivery tube 72 is advanced to a location where aortic graft 100 will be fastened to aortic wall 132. A loaded helical fastener 80 is oriented for deployment by applicator head 73, as shown by arrows C. Applicator head 73 is articuable in a clockwise and a counter-clockwise direction about the inner surface of graft 100. The surface of inner diameter 84 and penetration limit end 82 of helical fastener 80 have a rectangular configuration for cooperative engagement with drive assembly 76, drive assembly 76 also having a rectangular configuration at its distal end (FIG. 17). It is contemplated that the remainder of drive assembly 76 may not be in cooperative engagement with the surface of inner diameter 84. Helical fastener 80 has a substantially circular cross-section. It is envisioned that other cross-sectional configurations may be used that are suitable for fastening.

With reference to FIG. 15 and 16, handle 144 is manipulated to advance drive assembly 76. A torque is applied to handle 144 transmitting a rotational force from the proximal end to the distal end of drive assembly 76. The rectangular configuration of drive assembly 76 cooperates with the rectangular configuration of the surface of inner diameter 84 causing rotational movement of helical fastener 80. The sharpened distal end 81 of helical fastener 80 contacts the interior wall 102 of aortic graft 100 thereby facilitating deployment of fastener 80 into aortic graft 100 and aortic wall 132. Helical fastener 80 penetrates aortic graft 100 and aortic wall 132 to penetration limit end 82 thereby fastening aortic graft 100 to aortic wall 132.

In the embodiment shown in FIG. 19, delivery tube 72 cooperates with elongate control 68 at junction 69. Junction 69 facilitates rotation of delivery tube 72 and drive assembly 76 positioned coaxially therewithin, to a location for deployment of helical fasteners 80, as shown in FIG. 19 by arrow D. Junction 69 rotates by manipulation of expandable portion control 150, as shown in FIG. 18. Delivery tube 72 is retracted from the fastening site and loaded with another helical fastener 80 for subsequent deployment at another location along the diameter of aortic graft 100. As many helical fasteners 80

may be deployed as are necessary to adequately fasten aortic graft 100 to aortic wall 132. Fastening in this manner prevents periprosthetic losses and accidental migration of aortic graft 100. It is contemplated that multiple helical fasteners 80 may be loaded into endovascular fastener applicator 50.

5 In another embodiment, as shown in FIGS. 20-27, endovascular fastener applicator 50 positions aortic graft 100 at the aneurysm site and in contact with aortic wall 132. Referring to FIG. 20 aortic graft 100 includes band 104 having anchor pads 107 implanted therewithin. As shown in FIG. 23, anchor pads 107 are implanted circumferentially about band 104. Band 104 may be fabricated from, such as, for
10 example, polytetrafluoroethylene. Anchor pads 107, are implanted within band 104 corresponding to interstitial regions 70 located between support members 67 of expandable portion 66. Referring to FIG. 23, pads 107 have a substantially circular configuration. It is envisioned that the pads may have other configurations such as, for example, rectangular, elliptical, etc.

15 Anchor pads 107 cooperatively engage fastener guides 106 positioned at the distal end of drive assembly 76. Anchor pads 107 and fastener guides 106 cooperate to provide a guided deployment of helical fasteners 80 and facile release of drive assembly 76 from the aneurysm site. Referring to FIGS. 21 and 22, drive assembly 76 further includes multiple guide wires 77 releasably attached to fastener guides 106. Guide wires 77
20 facilitate guided travel of fasteners 80.

Referring back to FIG. 24, fastener guides 106 include anchor legs 108. Anchor legs 108 are resiliently biased so that upon deployment of helical fastener 80, anchor legs 108 are caused to collapse and release from band 104. Anchor legs 108 are connected to multiple guide wires 77 so that after collapse and release of anchor legs 108, multiple
25 guide wires 77 are retracted from the fastening site. Anchor pad 107 is retained within band 104 after helical fastener 80 is deployed.

As shown in FIG. 25, expandable portion 66 supports aortic graft 100 in contact with aortic wall 132. Applicator head 73 of delivery tube 72 is configured and

dimensioned to cooperate with inner diameter 84 to advance a helical fastener 80 over multiple guide wires 77, as shown by arrows E. As helical fastener 80 is deployed, anchor legs 108 are caused to collapse, shown by arrows F in FIG. 26. Delivery tube 72 causes rotational movement of helical fastener 80 and corresponding penetration of band 104, aortic graft 100 and aortic wall 132, facilitating fastening.

Delivery tube 72 is retracted subsequent to deployment of helical fastener 80 and multiple guide wire 77 is also retracted, as shown in FIG. 27, with helical fastener 80 in a deployed position. Delivery tube 72 is subsequently loaded with another helical fastener 80 for deployment from another of multiple guide wires 77. As many helical fasteners 80 may be deployed as are necessary to adequately fasten aortic graft 100 to aortic wall 132. It is contemplated that at least a portion of the fastener guides and/or guide wires may remain fixed to the prosthetic upon deployment of a fastener.

In another embodiment as shown in FIG. 28, control assembly 140 includes a handle 110 and a trigger 120 for controlling operation of endovascular fastener applicator 50. In this embodiment, handle 110 controls advancement of delivery tube 72 (not shown) and trigger 120 controls advancement of drive assembly 76 (not shown) and deployment of helical fasteners 80 (not shown).

In another embodiment, as illustrated in FIGS. 29-33, a plurality of helical fasteners 80 are loaded in endovascular fastener applicator 50 for deployment. As shown in FIG. 30, drive assembly 76 defines a channel 75 for accepting helical fasteners 80 (FIG. 31). In particular, penetration limit end 82 of helical fastener 80 slidably engages channel 75 providing a plurality of helical fasteners 80 for deployment, as shown in FIG. 29. Applicator head 73 of delivery tube 72 engages band 104, as shown in FIG. 32, and drive assembly 76 advances helical fasteners 80 to penetrate band 104, aortic graft 100 and aortic wall 132, shown by arrows G. As shown in FIG. 33, aortic graft 100 is fastened to aortic wall 132 of aorta 124 by helical fastener 80. After deployment of a helical fastener 80, delivery tube 72 is rotated to deploy another of the plurality of helical fasteners 80, consequently reloading is not required.

In another embodiment, as illustrated in FIGS. 34-51, expandable portion 66 is capable of moving between two extreme positions. A relaxed position, as shown in FIG. 35, and an expanded position, as shown in FIG. 34. In the embodiment illustrated in FIG. 34, expandable portion 66 includes support members 67 that define open interstitial regions 70.

As best shown in FIG. 36, outer sleeve 64 operatively engages with expandable portion 66 for controlling operation between the two extreme positions. Expandable portion 66 has an atraumatic head 200 attached to opening 210 defined at the distal end of expandable portion 66 and opening 212 defined at its proximal end for receiving applicator head 73 of delivery tube 72. Applicator head 73 includes ejection mount 250 for deployment of a plurality of helical fasteners 80 from drive assembly 76.

Ejection mount 250, as shown in FIG. 36, includes yoke 256 and ejection head 260. Yoke 256 engages penetration head 200 for coaxial positioning within expandable portion 66. Ejection head 260 is pivotally positioned within yoke 256. Ejection head 260 includes a cam divider 262 and a saw-toothed face 264. Ejection head 260 is capable of rotational movement relative to delivery tube 72 and pivotal movement between two extreme positions. A first extreme position is coaxial with delivery tube 72 and a second extreme position is perpendicular to the longitudinal axis of delivery tube 72 and in position to deploy a helical fastener 80.

With reference to FIGS. 37 and 38, drive assembly 76 includes distal drive 280, proximal drive 284, outer drive 285, ratchet assembly 286, spring 294 and washer 296. Distal drive 280 defines a slot 281 for receiving penetration limit end 82 for loading a plurality of helical fasteners 80. The plurality of helical fasteners 80 are spring loaded onto drive assembly 76 and separated from spring 294 by washer 296.

Distal drive 280 is operatively connected to ratchet assembly 286 which is operatively connected to proximal drive 284 and outer drive 285. Ratchet assembly 286 includes ratchet sleeve 287 which defines opening 288 for receipt of distal drive 280. Manipulation of proximal drive 284 causes movement of distal drive 280 to facilitate

deployment of helical fasteners 80. Ratchet sleeve 287 also defines opening 289 for receipt of proximal drive 284. Ratchet sleeve 287 is slidably received within ratchet retainer 290 for cooperative engagement with outer drive 285. Ratchet retainer 290 defines opening 291 for receiving ratchet arm 292.

As shown in FIGS. 39 and 40, ratchet arm 292 engages ejection head 260. Ratchet arm 292 is positioned within cam divider 262 in ejection head 260 and secured therein by set screw 298. It is contemplated that ratchet arm 292 is crimped in place within ejection head 260 and that no set screw is required. It is further contemplated that ratchet arm 292 may be fixed within ejection head 260 as is known by one skilled in the art. Manipulation of outer drive 285 engages ratchet retainer 290 and ratchet arm 292 causing pivotal movement of ejection head 260 relative to delivery tube 72.

As illustrated in FIGS. 41 and 42, delivery assembly 60 is positioned at the aneurysm site of abdominal aortic aneurysm 120. Aortic graft 100 is positioned for fastening to aortic wall 132 of aorta 124. Aortic graft 100 has band 104. Aortic graft 100 may also have gasket 105, as shown in FIG. 41, sewn to the outside diameter of aortic graft 100 to prevent leakage of fluid.

Expandable portion 66 is in a relaxed state, as shown in FIGS. 41 and 42. Aortic graft 100 is positioned at the abdominal aneurysm site and expandable portion 66 is caused to expand by axial motion of outer sleeve 64, shown by arrows I in FIG. 44 and by arrows H in FIG. 43, illustrating the outward force of support members 67 used to support aortic graft 100 in contact with aortic wall 132. Expandable portion 66 facilitates fastening of aortic graft 100 with aortic wall 132 for deployment of helical fasteners 80 by securing aortic graft 100 in contact with aortic wall 132. It is contemplated that helical fasteners 80 may be deployed from ejection mount 250 through interstitial regions 70 between support members 67. The helical fasteners 80 are deployed about the circumference of aortic graft 100 relative to the number of support members 67 and spacing of interstitial regions 70.

As shown in FIG. 45, drive assembly 76 is loaded with a plurality of helical

fasteners 80. Referring to FIG. 46, delivery tube 72 has an ejection arm 310 positioned at its distal end facilitating pivotal movement of ejection mount 250. An arm 292 functions as an ejection arm to ejection head 260. This provides extra holding force on the graft which pivots ejection head 260 positioned at its distal end. Ejection arm 310 includes a slider 312 received within a cam slot 300 defined by ejection head 260. Cam slot 300 further defines the relative movable limits of slider 312 and thus ejection arm 310.

Delivery tube 72 is manipulated advancing ejection arm 310 axially causing pivotal movement of ejection head 260, shown by arrow J, and positioning ejection head 260 for deployment of helical fasteners 80. Ejection head 260 is positioned in a substantially perpendicular orientation to the longitudinal axis of delivery tube 72.

It is contemplated that ejection arm 310 has alternate orientations for causing movement of ejection head 260. For example, in an alternate embodiment shown in FIG. 46A, ejection head 260 pivots within expandable portion 66 and is positioned at the center of expandable portion 66. Saw-toothed face 264 is positioned at a closer proximity to the inner surface of graft 100 for accurate deployment of a fastener. At the center position, ejection head 260 spans a diameter that expandable portion 66 supports aortic graft 100 in contact with aortic wall 132. In this embodiment, ejection arm 310 is fixed at a maximum angle relative to delivery tube 72.

Drive assembly 76 is manipulated so that ejection head 260 engages band 104 of aortic graft 100 for deployment of helical fasteners 80, as illustrated in FIG. 47. Outer drive 285 and proximal drive 284 are advanced, shown by arrows K. Ejection arm 292 correspondingly axially positions saw-tooth face 264 of ejection head 260 to contact band 104 of aortic graft 100, as shown by arrow L. Ejection arm 292 may also cause rotational movement of ejection head 260 and saw-tooth face 264 for engaging aortic graft 100.

With reference to FIG. 48, distal drive 280 advances and is rotated causing helical fasteners 80 to penetrate and fasten aortic graft 100 and aortic wall 132, as shown by arrow M.

As shown in FIG. 49, delivery tube 72 is manipulated so that ejection arm 310

pivotaly retracts ejection head 260 to a position substantially parallel to the longitudinal axis of delivery tube 72, as shown by arrows MM.

FIG. 50 illustrates a retracted ejection mount 250 subsequent to deployment of one of a plurality of helical fasteners 80. A rotational force is transmitted from the proximal end to the distal end of drive assembly 76, shown by arrows N, thereby driving and axially advancing another of the plurality of helical fasteners 80, shown by arrows P, for deployment by ejection head 260 at a new deployment site.

FIG. 51 shows ejection head 260 positioned in a substantially perpendicular orientation to the longitudinal axis of delivery tube 72(not shown). Ejection head 260 is rotated to a new deployment site to deploy another of the plurality of helical fasteners 80 (not shown). As many helical fasteners 80 may be deployed as are necessary to adequately fasten aortic graft 100 to aortic wall 132.

It will be understood that various modifications may be made to the embodiments disclosed herein. For example, while specific preferred embodiments of the endovascular fastener applicator have been described in detail, structures that perform substantially the same function in substantially the same way to achieve substantially the same result may also be used. For example, the expandable portion may include expanding wires for supporting a prostheses in contact with a vessel wall. Also the fastener guide may be implanted completely through the thickness of the aortic graft. Further, the helical fasteners may be constructed from various suitable materials or may embody one continuous fastener that is severable at the point of insertion. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments, those skilled in the art will envision other modifications within the scope and spirit of the present disclosure.

WHAT IS CLAIMED IS:

5
1. An endovascular fastener applicator for endoluminally fastening a
prosthetic to a vessel with a fastener, the applicator comprising:

a tubular body configured for positioning within a vessel;

10 an expandable portion disposed adjacent a distal end of the tubular body
and being deployable to support a prosthetic in contact with an inner surface of a vessel;
and

a drive assembly for advancing a fastener into the prosthetic.

15 2. An endovascular fastener applicator as recited in claim 1, further
comprising a control assembly operatively connected to said drive assembly for
extracorporeal control of the applicator.

20 3. An endovascular fastener applicator as recited in claim 1, further
comprising a delivery tube being disposed for movement within the tubular body and
defining a channel for movement of the drive assembly therewithin, the delivery tube
being configured for advancing a fastener within the tubular body.

4. An endovascular fastener applicator as recited in claim 1, further comprising an elongate control positioned for movement within the tubular body, wherein the expandable portion is operatively connected to a distal end of the tubular body and a distal end of the elongate control, the tubular body and the elongate control being manipulable to facilitate support of the prosthetic in contact with an inner surface of a vessel.

5. An endovascular fastener applicator as recited in claim 4, wherein the elongate control is coaxially disposed with the tubular body.

6. An endovascular fastener applicator as recited in claim 3, wherein the delivery tube is coaxially disposed with the tubular body.

7. An endovascular fastener applicator as recited in claim 1, wherein the drive assembly is coaxially disposed with the tubular body.

8. An endovascular fastener applicator as recited in claim 1, wherein at least a portion of the applicator is fabricated from a shape memory material.

9. An endovascular fastener applicator as recited in claim 1, wherein the drive assembly includes a curved portion oriented at an angle of substantially 90° from a

longitudinal axis defined by the tubular body.

10. An endovascular fastener applicator as recited in claim 1, wherein the drive assembly is configured for axial and rotational motion.

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11. An endovascular fastener applicator as recited in claim 3, wherein the delivery tube includes an applicator head configured to facilitate deployment of a fastener.

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12. An endovascular fastener applicator as recited in claim 1, wherein the expandable portion includes support members that define open interstitial regions therebetween.

15

13. An endovascular fastener applicator as recited in claim 12, wherein the support members comprise a plurality of flexible wires.

14. An endovascular fastener applicator as recited in claim 12, wherein the support members comprise a plurality of flexible tapes.

20

15. An endovascular fastener applicator as recited in claim 11, wherein the applicator head has a substantially perpendicular orientation to a longitudinal axis

defined by the delivery tube.

16. An endovascular fastener applicator as recited in claim 1, wherein the drive assembly includes a drive rod having a rectangular cross-section, the drive rod cooperating with an inner diameter of a fastener whereby movement of the drive rod causes advancement of a fastener.

17. An endovascular fastener applicator as recited in claim 1, wherein the applicator is configured to deploy multiple fasteners.

18. An endovascular fastener applicator as recited in claim 1, wherein the drive assembly includes at least one fastener guide configured to guide advancement of a fastener, each fastener guide cooperates with a prosthetic for guiding advancement of a fastener.

19. An endovascular fastener applicator as recited in claim 2, wherein the control assembly includes a handle having a pistol-grip trigger configuration.

20. An endovascular fastener applicator as recited in claim 11, wherein the applicator head includes an ejection mount disposed for movement relative to a prosthetic and configured for deployment of a plurality of helical fasteners, the ejection

mount has an ejection head with a saw toothed face configured for engaging a prosthetic, facilitating uniform deployment of each fastener deployed.

21. An endovascular fastener applicator as recited in claim 20, further
5 including a ratchet assembly configured to facilitate movement of the ejection mount.

22. An endovascular fastener applicator system for repairing a damaged
portion of a vessel, the system comprising:

at least one helical fastener, each helical fastener having a penetrating end
10 and a limiting end;

a prosthetic; and

an endovascular fastener applicator including:

a tubular body configured for positioning within a vessel;

a delivery tube being disposed for movement within the tubular body and
15 configured for advancing each helical fastener within the tubular body, the delivery tube
including an applicator head adjacent a distal end thereof, the applicator head being
configured for deploying each helical fastener and having a substantially perpendicular
orientation relative to a longitudinal axis defined by the delivery tube;

an expandable portion being operatively connected adjacent the distal end
20 of the tubular body and including support members that define open interstitial regions,
the support members being configured to support the prosthetic in contact with an inner

surface of the vessel;

a drive assembly being disposed for axial and rotational movement within the delivery tube, the drive assembly including a drive rod configured to cooperate with the helical fastener for advancing the helical fastener and facilitating deployment thereof to the prosthetic; and

a control assembly operatively connected to the drive assembly for extracorporeal control of the applicator.

23. An endovascular fastener applicator system as recited in claim 22, wherein the applicator head is configured for engaging an interior portion of the prosthetic to facilitate uniform deployment of each helical fastener.

24. An endovascular fastener applicator system as recited in claim 22, wherein the drive rod has a cross-section corresponding to an interior cross-section defined by each helical fastener and in cooperation facilitates advancement and deployment of each helical fastener.

25. An endovascular fastener applicator system recited in claim 22, wherein the prosthetic includes an interior band having anchor pads circumferentially spaced about and implanted within the band, the pads corresponding to the open interstitial regions of the expandable portion, the drive assembly further including guide

wires being configured for guiding advancement of each helical fastener and having anchor legs adjacent a distal end of each of the guide wires, the anchor legs releasably engaging the anchor pads prior to deployment of each helical fastener and being retractable from the prosthetic upon deployment of each helical fastener.

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26. An endovascular fastener applicator system as recited in claim 22, wherein the applicator head includes an ejection mount being configured for deploying at least one helical fastener and movable relative to an interior circumference of the prosthetic for deploying each helical fastener, the ejection mount including an ejection head having a saw-toothed face for engaging the internal circumference of the prosthetic, the ejection head facilitating uniform deployment of each helical fastener.

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27. An endovascular fastener applicator system as recited in claim 26, further including a ratchet assembly being configured to facilitate movement of the ejection mount.

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28. A method for endoluminally repairing a damaged portion of a vessel, the method comprising the steps of:

providing an endovascular fastener applicator for endoluminally fastening a prosthetic to a vessel with a fastener, the applicator including: a tubular body configured for positioning within a vessel, an expandable portion disposed adjacent a

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distal end of the tubular body and being deployable for supporting a prosthetic in contact with an inner surface of a vessel, and a drive assembly for advancing a fastener into a prosthetic;

5 expanding the expandable portion adjacent an inner surface of the vessel to facilitate support of a prosthetic in contact with a vessel;

 advancing a fastener with the drive assembly to a site for deployment of the fastener; and

 deploying the fastener with the drive assembly to penetrate the prosthetic.

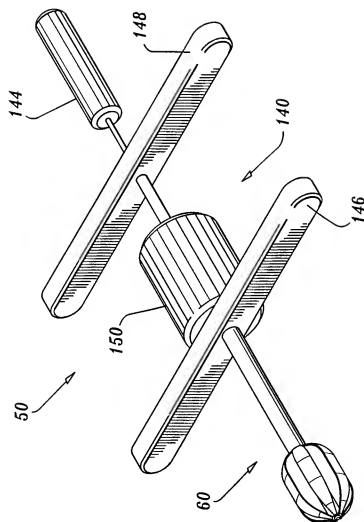
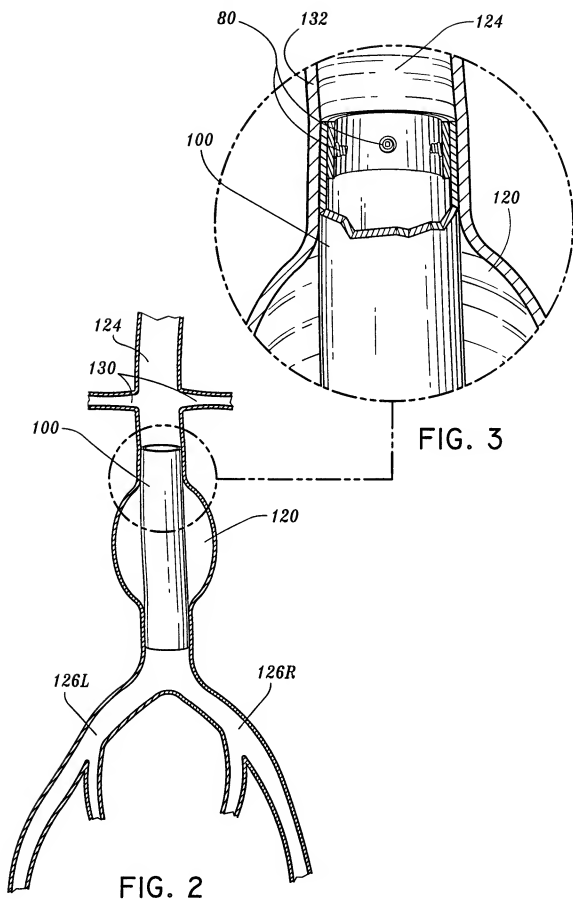


FIG. 1

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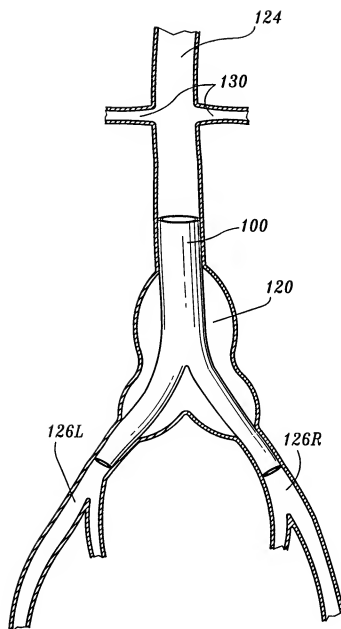


FIG. 4

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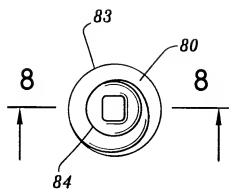


FIG. 7

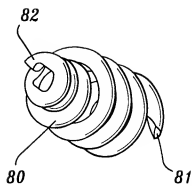


FIG. 5

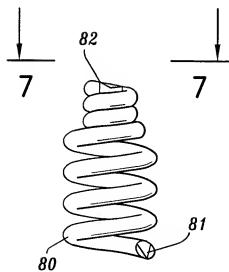


FIG. 6

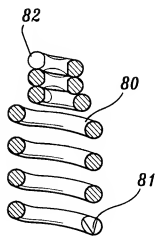


FIG. 8

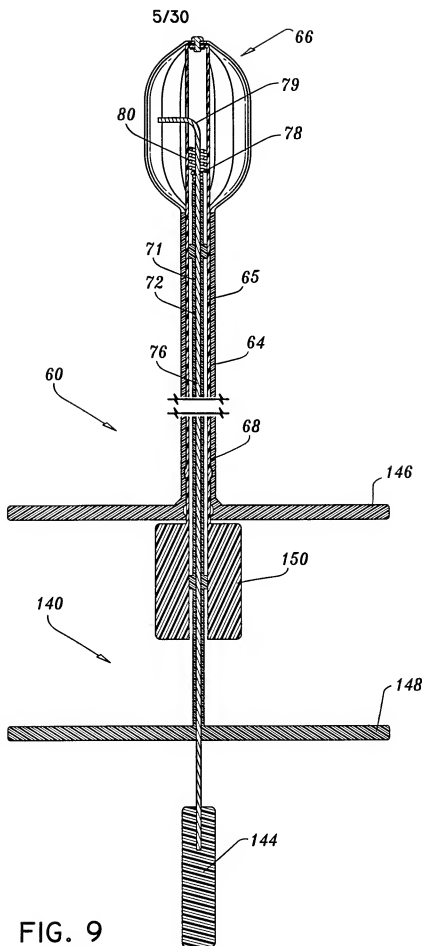


FIG. 9

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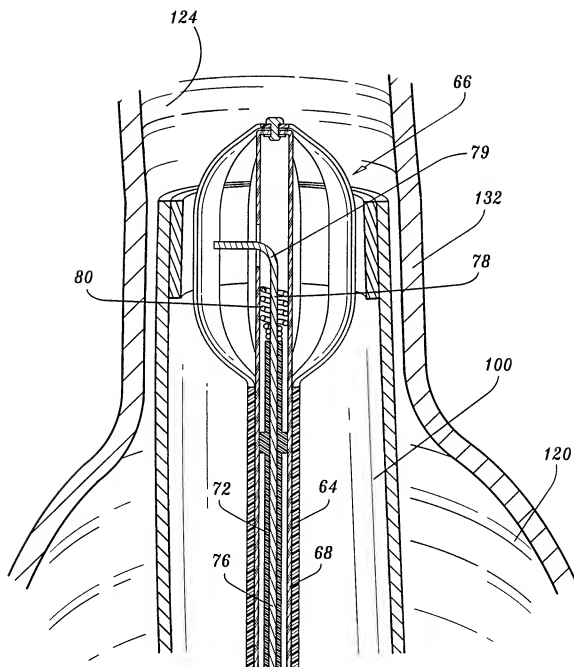
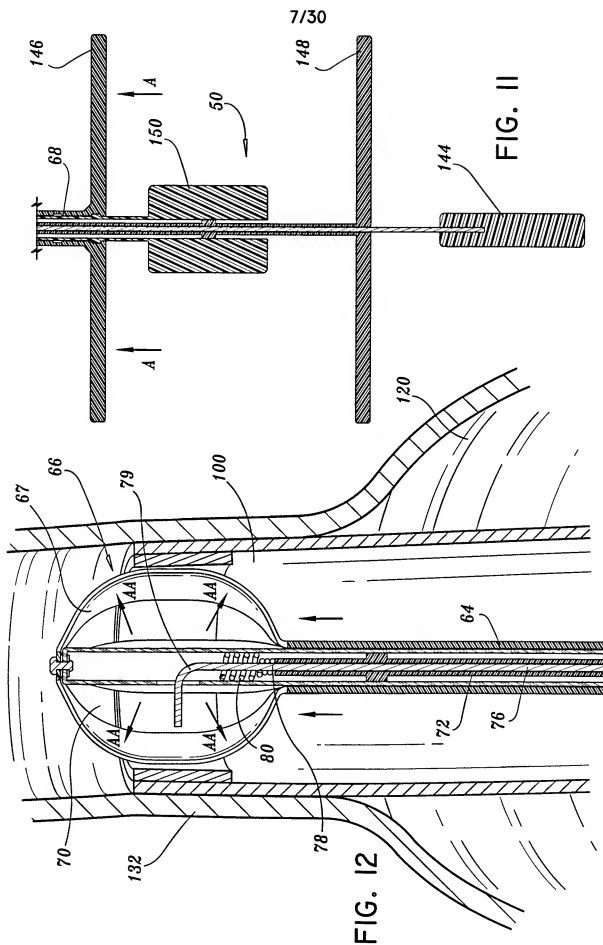
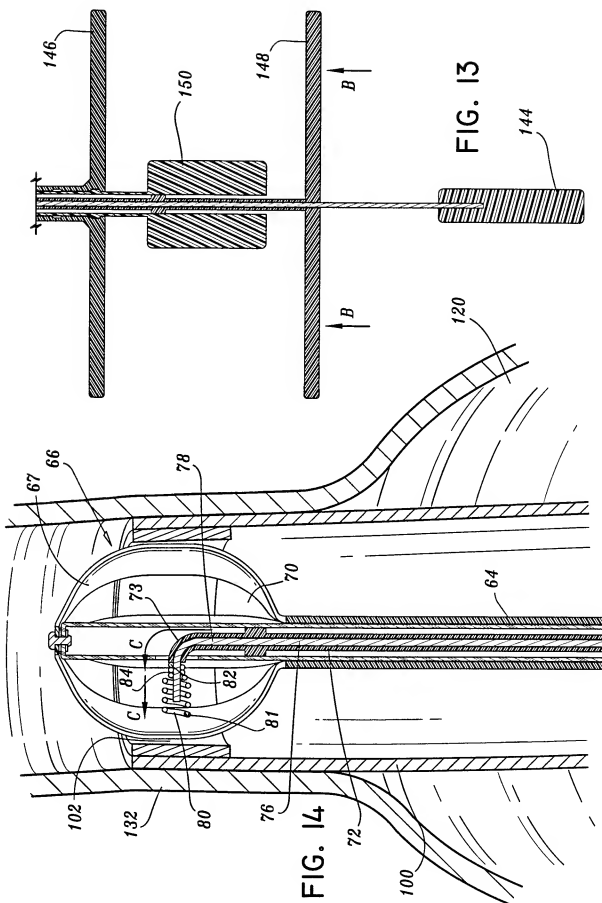


FIG. 10



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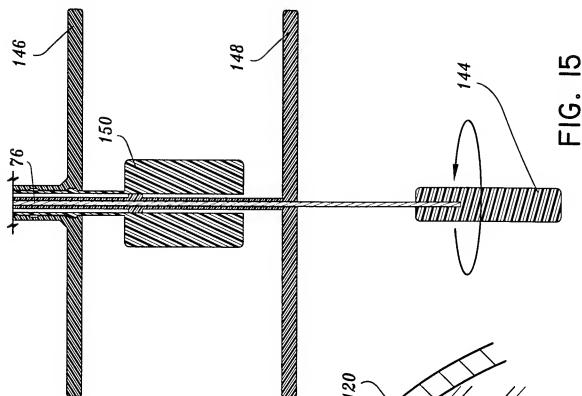


FIG. 15

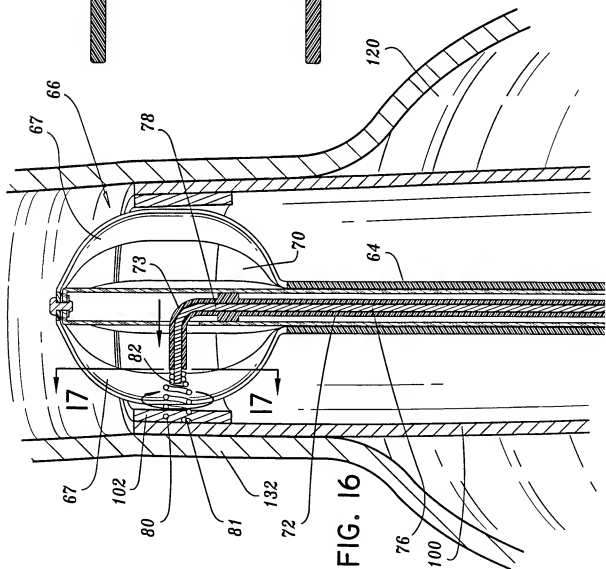


FIG. 16

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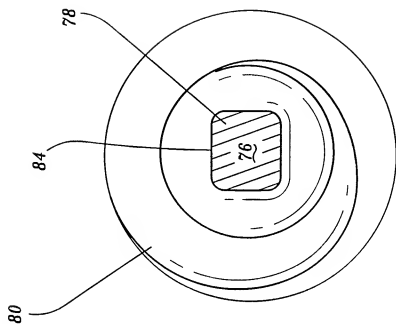


FIG. 17

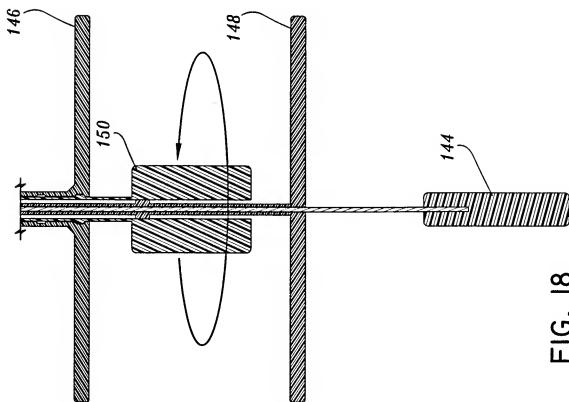
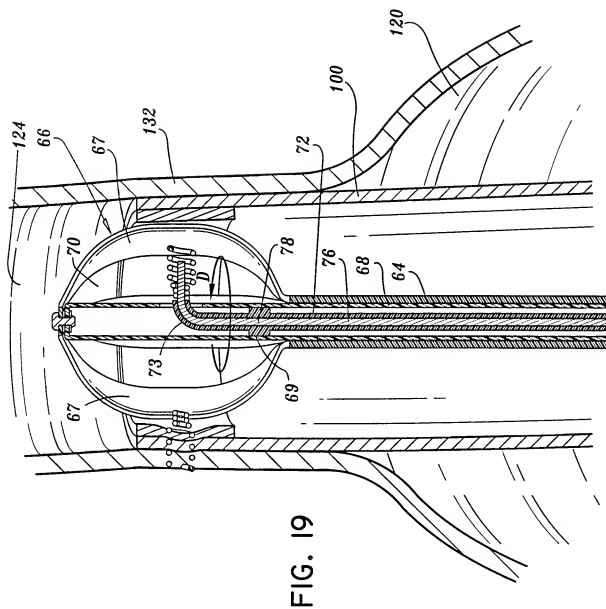


FIG. 18

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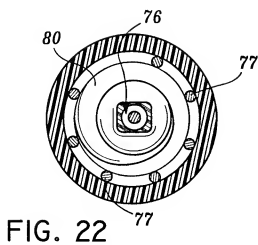


FIG. 22

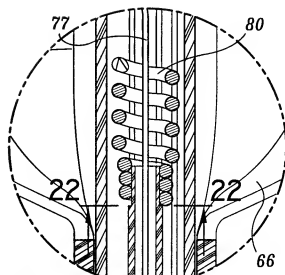


FIG. 21

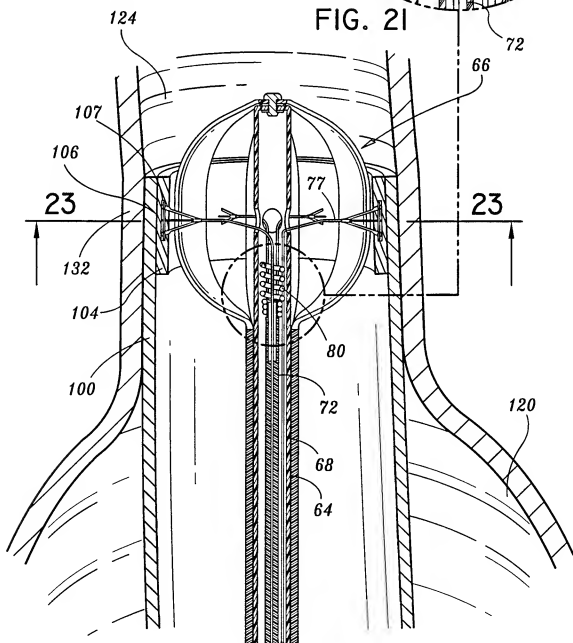


FIG. 20

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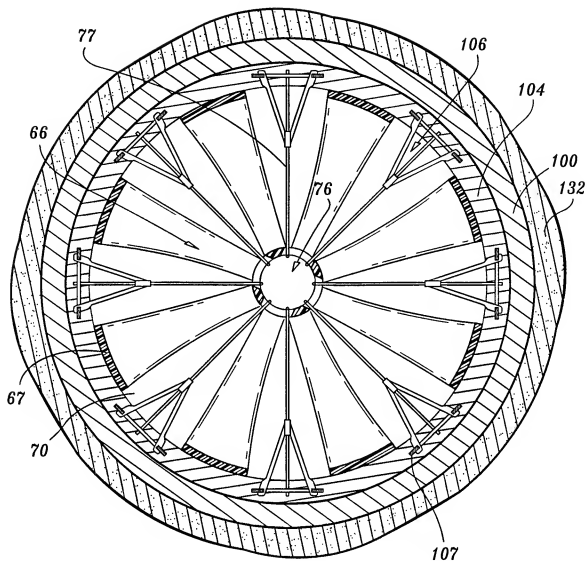


FIG. 23

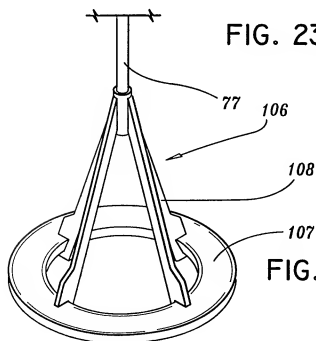


FIG. 24

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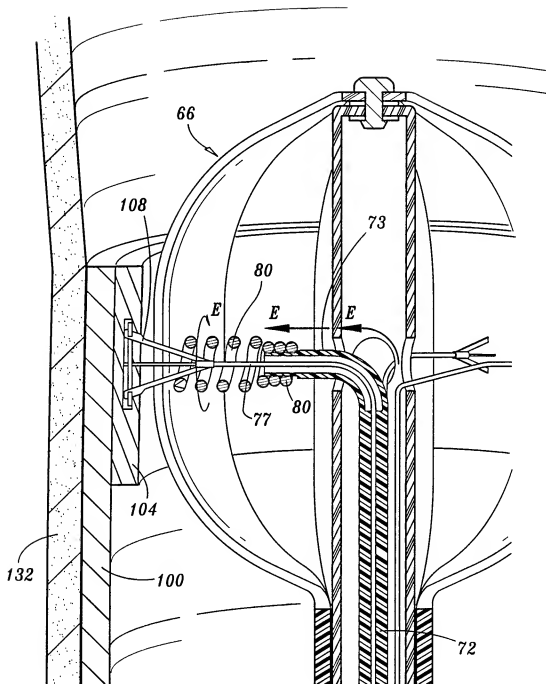


FIG. 25

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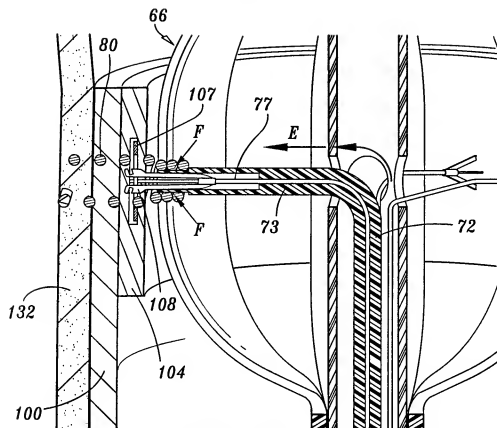


FIG. 26

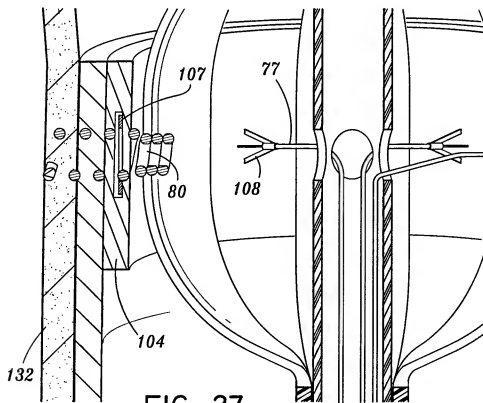


FIG. 27

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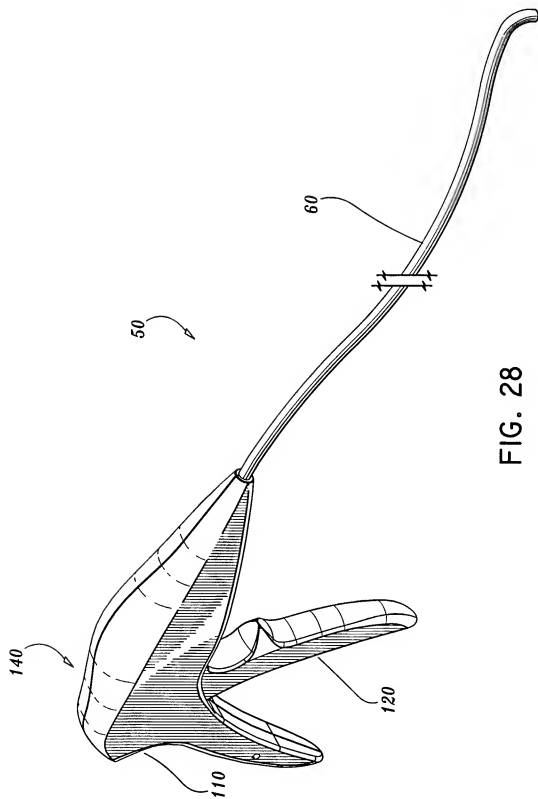


FIG. 28

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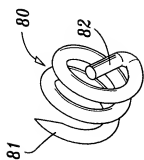


FIG. 31

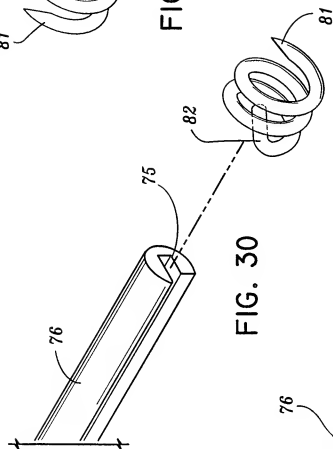


FIG. 30

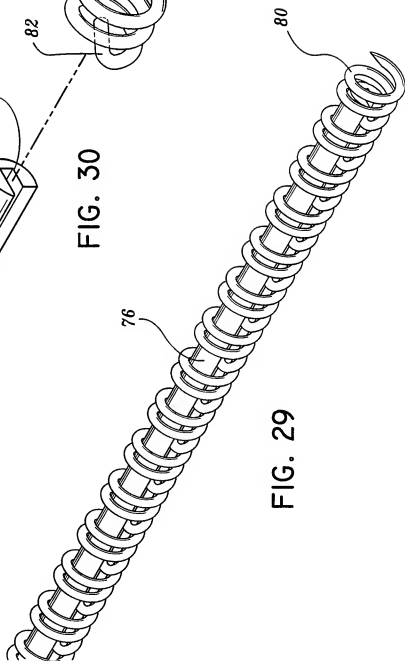


FIG. 29

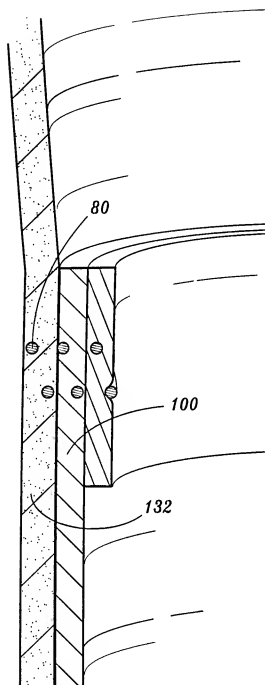


FIG. 33

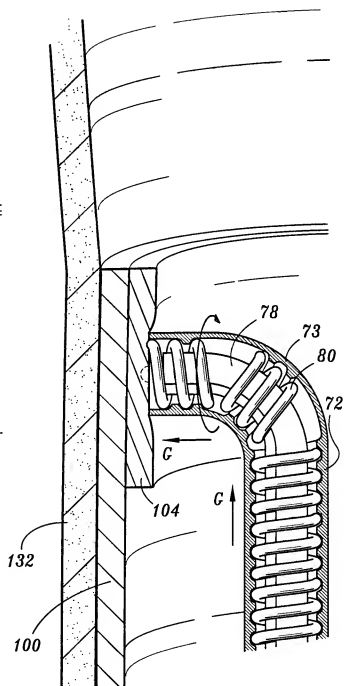
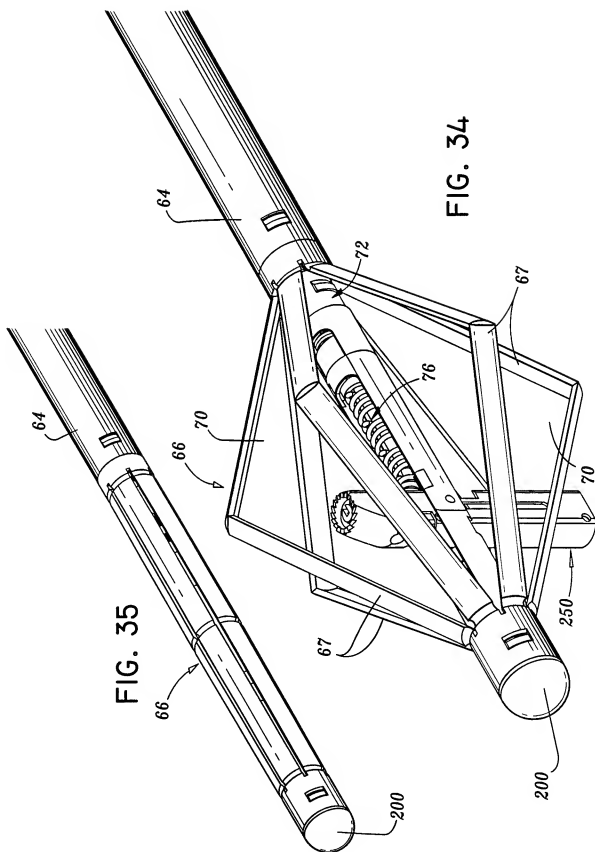
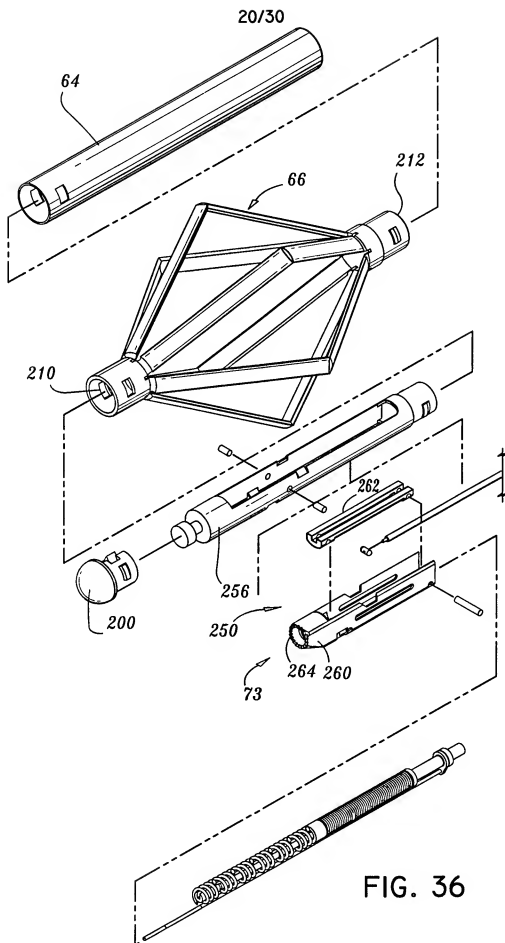


FIG. 32

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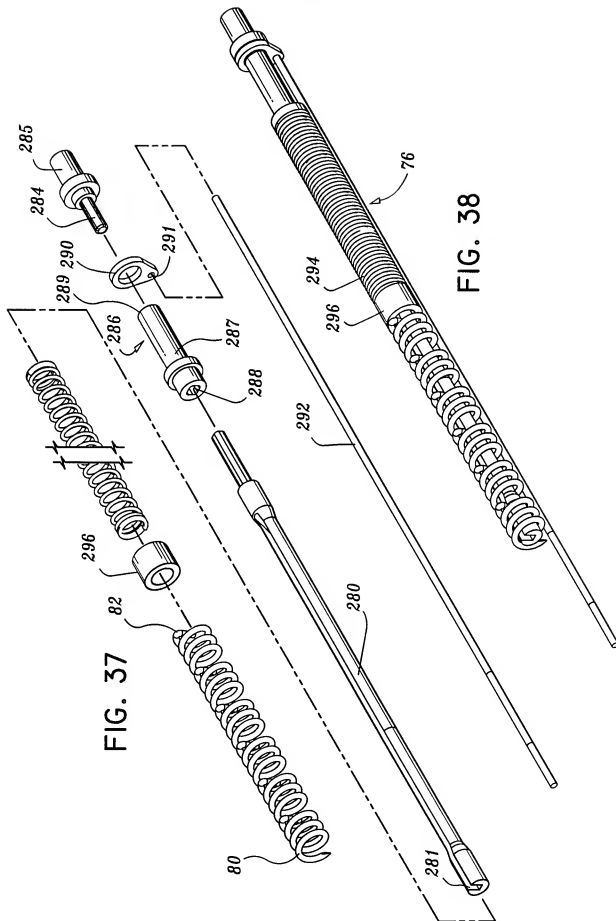
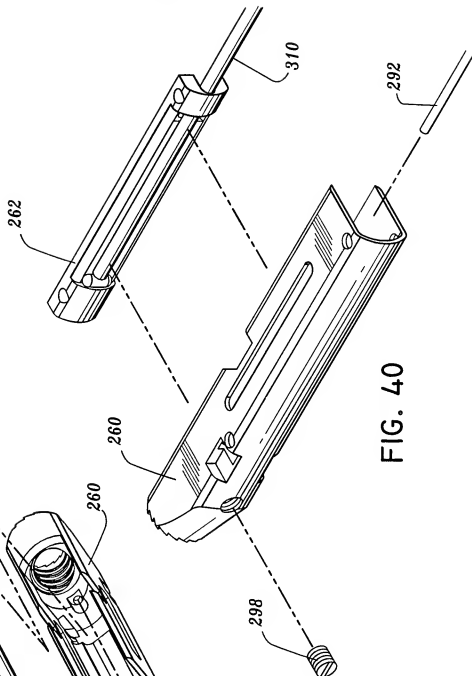
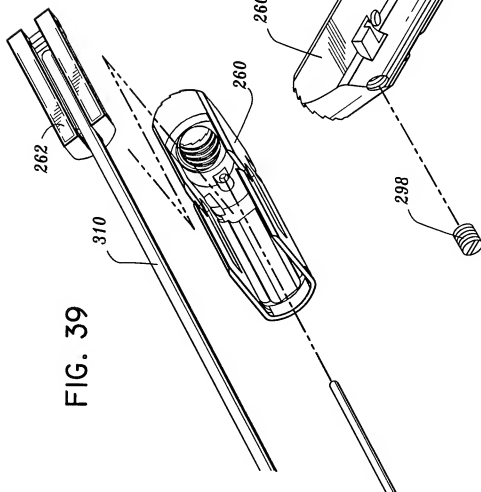


FIG. 38

FIG. 37

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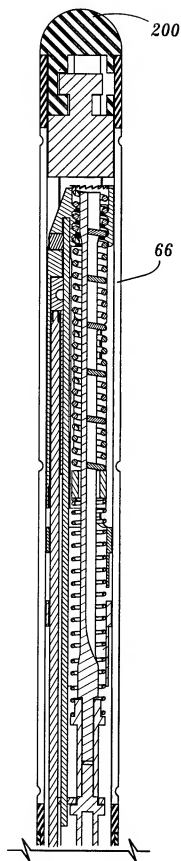


FIG. 42

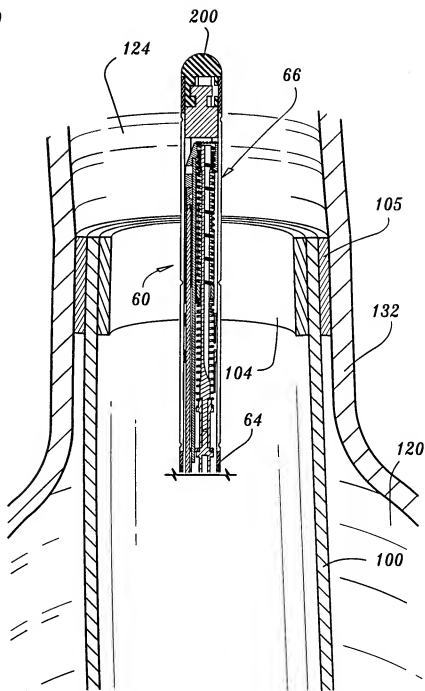


FIG. 41

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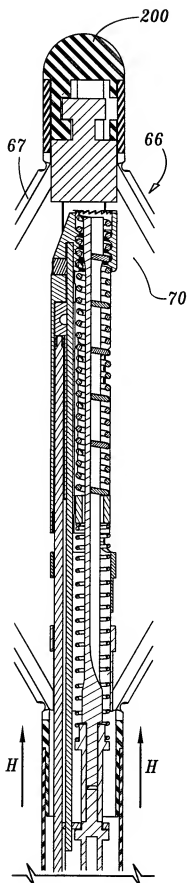


FIG. 44

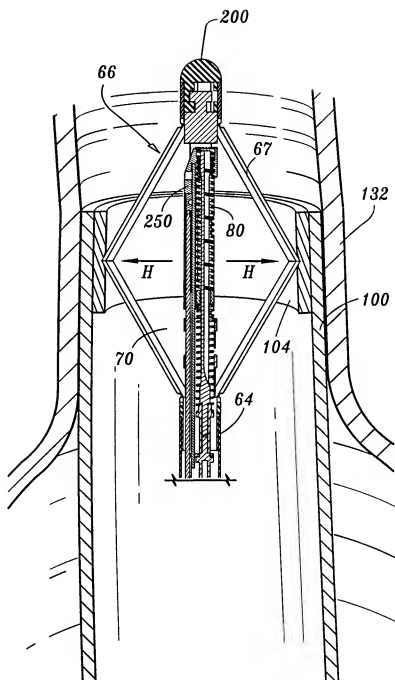


FIG. 43

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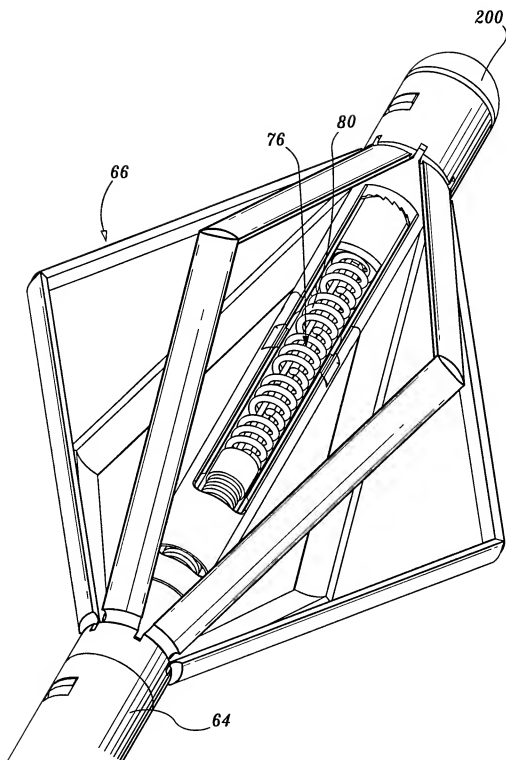


FIG. 45

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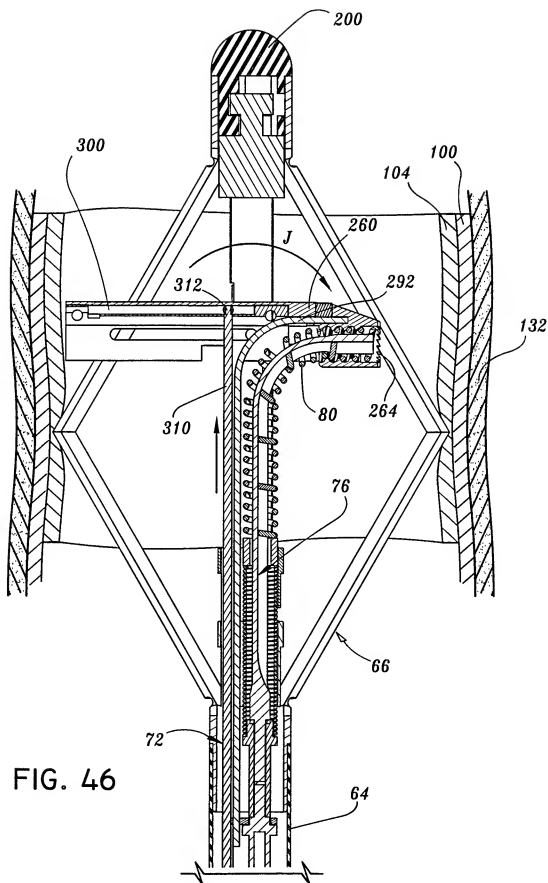


FIG. 46

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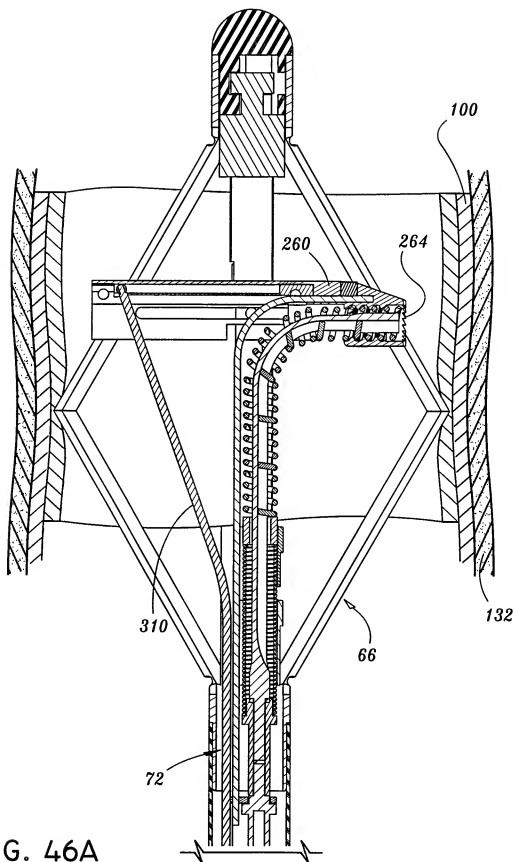


FIG. 46A

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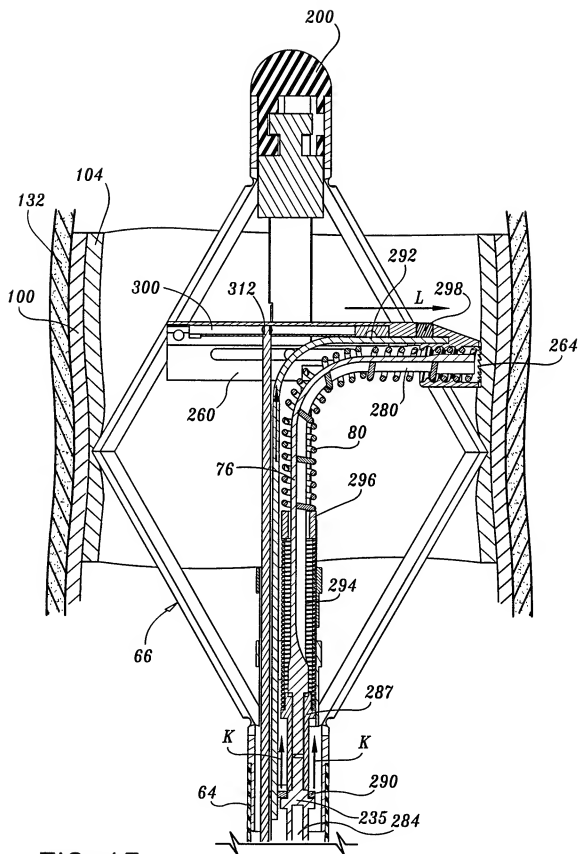


FIG. 47

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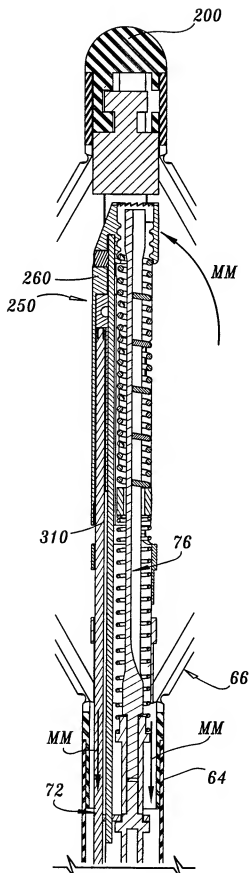


FIG. 49

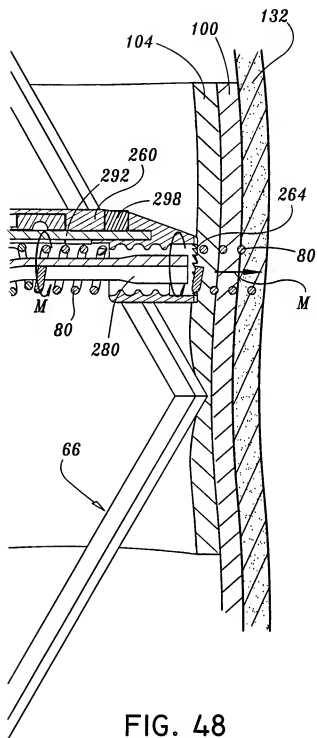


FIG. 48

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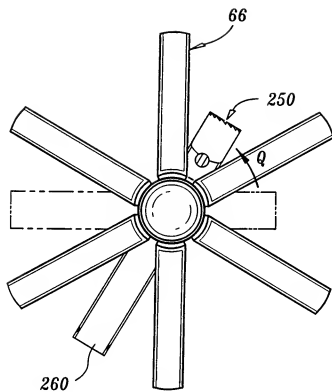


FIG. 51

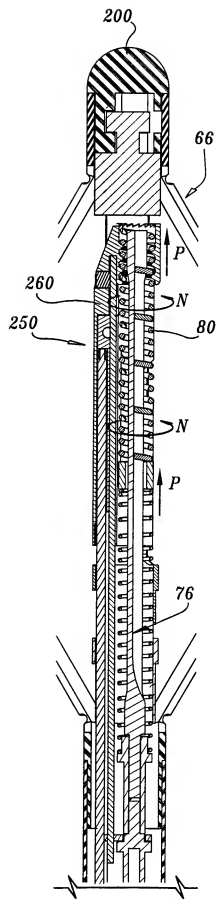


FIG. 50

INTERNATIONAL SEARCH REPORT

 International application No.
 PCT US99 21414

A. CLASSIFICATION OF SUBJECT MATTER

 IPC(6) A61B 17 08
 US CL 606 153

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/153

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y, P	US 5,824,041 A (LENEKER et al.) 20 October 1998, Fig. 2, and col. 7 lines 9-48.	1-28
Y	US 5,700,269 A (PINCHUK et al.) 23 December 1997, Fig. 9-12; and col. 6 lines 7-57.	1-28
Y, E	US 5,957,940 A (TANNER et al.) 28 September 1999, cols. 8-28.	1-28



Further documents are listed in the continuation of Box C.



See patent family annex.

*

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Z

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Date of the actual completion of the international search

20 OCTOBER 1999

Date of mailing of the international search report

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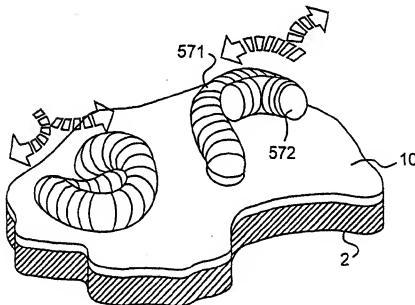
(51) International Patent Classification ⁶ : A61B 17/00	A1	(11) International Publication Number: WO 00/35350 (43) International Publication Date: 22 June 2000 (22.06.00)
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(21) International Application Number: PCT/US99/29348

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(30) Priority Data:
09/213,233 17 December 1998 (17.12.98) US(71) Applicant: EVA CORPORATION [US/US]; Hugh, Trout, III,
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UT 84321 (US).(74) Agents: COYNE, Patrick, J. et al.; Collier, Shannon, Rill &
Scott, PLLC, Suite 400, 3050 K Street, N.W., Washington,
DC 20007 (US).(81) Designated States: JP, European patent (AT, BE, CH, CY, DE,
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(54) Title: SURGICAL FASTENER



(57) Abstract

A fastener (510) comprises a flexible fastening assembly for securing a surgical component (20) to the vessel wall (2) under a compressive force. The fastening assembly has a first portion (542) located on one side of the surgical component (20), and the vessel wall (2); a second portion (543) located on another side of the surgical component (20); the vessel wall (2), and an intermediate portion (541) connecting to the first portion (542), and the second portion (543); the intermediate portion (541) extending through the vessel wall (2), and the surgical component (20). The fastener (510) further includes a control assembly for controlling the compression of the fastener (510).

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SURGICAL FASTENER

Background of the Invention

1. Field of the Invention

The present invention relates to methods and apparatus for the repair of abdominal aortic aneurysms using a novel prosthetic tube graft within the abdominal aorta.

2. Description of Related Art

An aneurysm is a ballooning of the wall of an artery resulting from the weakening of the artery due to disease or other conditions. Left untreated, the aneurysm will frequently rupture, resulting in loss of blood through the rupture and death.

Aortic aneurysms are the most common form of arterial aneurysm and are life threatening. The aorta is the main artery which supplies blood to the circulatory system. The aorta arises from the left ventricle of the heart, passes upward and bends over behind the heart, and passes down through the thorax and abdomen. Among other arterial vessels branching off the aorta along its path, the abdominal aorta supplies two side vessels to the kidneys, the renal arteries. Below the level of the renal arteries, the abdominal aorta continues to about the level of the fourth lumbar vertebrae (or the navel), where it divides into the iliac arteries. The iliac arteries, in turn, supply blood to the lower extremities and perineal region.

It is common for an aortic aneurysm to occur in that portion of the abdominal aorta between the renal arteries and the iliac arteries. This portion of the abdominal aorta is particularly susceptible to weakening, resulting in an aortic aneurysm. Such an aneurysm is often located near the iliac arteries. An aortic aneurysm larger than about 5 cm in diameter in this section of the aorta is ominous. Left untreated, the aneurysm may rupture, resulting in rapid, and usually fatal, hemorrhaging. Typically, a surgical procedure is not performed on aneurysms smaller than 5 cm because no statistical benefit exists in performing such procedures.

Aneurysms in the abdominal aorta are associated with a particularly high mortality rate; accordingly, current medical standards call for urgent operative repair. Abdominal surgery, however, results in substantial stress to the body. Although the mortality rate for an aortic aneurysm is extremely high, there is also considerable mortality and morbidity associated with open surgical intervention to repair an aortic aneurysm. This intervention involves penetrating the abdominal wall to the location of the aneurysm to reinforce or replace the diseased section of the aortic aneurysm. A prosthetic device, typically a synthetic tube graft, is used for this purpose. The graft serves to exclude the aneurysm from the circulatory system, thus relieving pressure and stress on the weakened section of the aorta at the aneurysm.

Repair of an aortic aneurysm by surgical means is a major operative procedure. Substantial morbidity accompanies the procedure, resulting in a protracted recovery period. Further, the procedure entails a substantial risk of mortality. While surgical intervention may be indicated and the surgery carries attendant risk, certain patients may not be able to tolerate the stress of intra-abdominal surgery. It is, therefore, desirable to reduce the mortality and morbidity associated with intra-abdominal surgical intervention.

In recent years, methods have been developed to attempt to treat an aortic aneurysm without the attendant risks of intra-abdominal surgical intervention. Among them are inventions disclosed and claimed in Kornberg, U.S. Patent No. 4,562,596 for Aortic Graft, Device and Method for Performing an Intraluminal Abdominal Aortic Aneurysm Repair; Lazarus, U.S. Patent No. 4,787,899 for Intraluminal Graft Device, System and Method; and Taheri, U.S. Patent No. 5,042,707 for Intravascular Stapler, and Method of Operating Same.

Kornberg discloses an aortic graft comprising a flexible tubular material having a plurality of struts to lend the graft stability and resiliency. The struts have angled hooks with barbs at their upper ends which are securely attached to the inside of the aorta above the aneurysm. Kornberg's graft is inserted using a tubular device also disclosed in his patent. Kornberg, however, only anchors the proximal end of the graft. Kornberg claims that the downward flow of blood holds the distal graft securely in place, so that no mechanical attachment is necessary distally. The blood pressure in the abdominal aorta, however, is

typically in the magnitude of 130 mm of mercury (Hg). In spite of the direction of flow of blood through the graft, proximal to distal, substantial back pressure within the aneurysm will result unless the distal end is also mechanically attached to the aorta in a manner that prevents substantial leakage of blood between the graft and the aorta. Without distal
5 attachment, the device of Kornberg will not effectively exclude the weakened arterial wall at the site of the aneurysm from the forces and stress associated with the blood pressure.

Lazarus discloses a grafting system that employs a plurality of staples mounted in the proximal end of the graft. Lazarus's staples are forced through the aorta wall by means of a balloon catheter. As does Kornberg, Lazarus discloses staples mounted only in the proximal
10 end of the graft. There is no teaching or suggestion in Lazarus, U.S. Patent No. 4,787,899 as to the desirability of, let alone means for, mechanically attaching the graft to the distal aorta below the level of the aneurysm.

Taheri discloses an articulatable stapler for implanting a graft in a blood vessel. The stapler is in the form of an elongated catheter with a plurality of segments mounted on the
15 distal end of the catheter. The segments have beveled faces and are connected to each other by hinges. A stylet runs through the catheter to the most distal segment. The most distal segment is moved, in conjunction with the other segments, into a firing position that is substantially perpendicular to the main catheter body by the action of pulling on the stylet. The staple is implanted by using two other stylets which act as fingers to bend the staple into
20 its attachment position.

Taheri, however, appears to be a single-fire design which can only implant one staple at a time. After each stapler is implanted, Taheri's design apparently requires that the catheter be removed before another staple is loaded. In addition, Taheri's does not teach or suggest an appropriate density of staples to secure a graft against the pulsatile blood flow of the aorta.
25 Pressures within the aorta range from 120 mm Hg pressure to 200 mm Hg pressure. Without adequate attachment, the graft may leak around the edges continuing to allow life threatening pressures to develop in the aneurysm, and may not even remain in place.

Hence, although in recent years certain techniques have been developed that may reduce the stress, morbidity, and risk of mortality associated with surgical intervention to

repair aortic aneurysms, none of the systems that have been developed effectively treat the aneurysm and exclude the affected section of aorta from the pressures and stresses associated with circulation. None of the devices disclosed in the references provide a reliable and quick means to reinforce an aneurysmal artery. In addition, all of the prior references require a sufficiently large section of healthy aorta surrounding the aneurysm to ensure attachment of the graft. The neck of the aorta at the cephalad end (i.e., above the aneurysm) is usually sufficient to maintain a graft's attachment means. However, when an aneurysm is located near the iliac arteries, there may be an ill-defined neck or no neck below the aneurysm. Such an ill-defined neck would have an insufficient amount of healthy aortic tissue to which to successfully mount a graft. Furthermore, much of the abdominal aorta wall may be calcified which may make it extremely difficult to attach the graft to the wall.

There are a number of shortcomings with the presently available graft products and their fixation within the abdominal aorta. Although sizing of "tube" or "bifurcated" grafts is radiographically assessed prior to surgery, it is necessary for the surgeon to have a large selection of graft lengths and diameters on hand to ensure an appropriate surgical outcome. Additional shortcomings include the placement of a "circular" profile graft with an associated fixation device within an essentially "ovoid" profile vessel and the use of attachment means which fasten only to the insubstantial, structurally compromised (diseased) intima and media levels of the vessel wall. Research has exposed yet another problem which indicates that the necks of the post-surgical aorta increase in size for approximately twelve months, regardless of whether the aneurysm experiences dimensional change. This phenomenon can result in perigraft leaks and graft migration.

There are a number of currently available scanning technologies that facilitate the pre-surgical assessment of abdominal aortic aneurysms. These include: computed tomography; magnetic resonance angiography; computed angiography; sonography including Doppler, and color flow; abdominal aortography; contrast arteriography; magnetic resonance imaging (i.e., MRI); and echocardiography. The images gained by these scanning technologies are informative, but are open to multiple interpretations as they do not provide direct viewing of the portion of the aorta to be repaired. Furthermore, the performance of the

procedures for these technologies may be injurious to the patient and in other instances impractical.

Objects of the Invention

5 It is therefore an object of the present invention to provide a new and improved method of repairing an abdominal aortic aneurysm.

It is another object of the present invention to provide an apparatus for facilitating the repair of an abdominal aortic aneurysm.

It is another object of the present invention to provide a graft for the repair of an abdominal aortic aneurysm.

10 It is an object of the present invention to provide an apparatus for the repair of the aneurysm that facilitates direct viewing of the area of the aneurysm to be repaired.

It is another object of the present invention to reduce the amount of damage to the aorta and associated vasculature while repairing the aneurysm.

15 It is another object of the present invention to facilitate direct viewing of the vessel wall surface to assist the medical practitioner (i.e., surgeon or interventional radiologist) in the repair of vessel.

It is an object of the present invention to exclude an aneurysm from the circulatory system.

20 It is an object of the present invention to create a device for the repair of an aneurysm that can, without negative consequences, navigate the vessels extending to and from the aorta.

It is another object of the present invention to localize a graft within the abdominal aorta between the proximal and distal ends of the aorta.

It is an object of the present invention to firmly fasten a graft to the adventitia of the vessel wall to prevent migration of the graft.

25 It is another object of the present invention to create a device to clearly visualize the surgical site during repair of the aneurysm.

It is another object of the present invention to create a uniform universal graft that is sized for use in a range of patients.

It is another object of the present invention to create a graft whose performance is not adversely effected by post surgical dimensional changes of the aortic necks.

It is another object of the present invention to create a device for the repair of the abdominal aortic aneurysm which may in addition to the classic femoral/common iliac introduction, also may be introduced via the axillary and/or brachial artery, which has not previously been contemplated.

It is another object of the present invention to provide a seal detail within an introducer sheath device that will significantly reduce blood loss during the repair procedure.

It is another object of the present invention to provide fastener assemblies that replace sutures.

It is another object of the present invention to provide a device that is capable of on board storage of a procedure specific quantity of fasteners so that it is not necessary to remove the device to reload during the repair procedure.

It is another object of the present invention to create a graft and a device for the repair of an aneurysm that reduces the invasiveness of current surgical procedures.

It is another object of the present invention to create a graft that is not dimension dependent (i.e., diameter/length) and which is adaptable to the patient environment.

Summary of the Invention

The present invention is directed to a fastener for use during a surgical procedure for securing a surgical component to a vessel wall. The fastener includes a flexible fastening assembly for securing the surgical component to the vessel wall under a compressive force. The fastening assembly has a first portion located on one side of the surgical component and the vessel wall, a second portion located on another side of the surgical component and the vessel wall, and an intermediate portion connecting to the first portion and the second portion, the intermediate portion extending through the vessel wall and the surgical component. The first portion, second portion and the intermediate portion act to apply a compressive force to the surgical component and the vessel wall to secure the surgical component to the vessel wall. The fastening assembly further includes at least one supplemental fastening assembly for securing the surgical component to the vessel wall, the

at least one supplemental fastening assembly being located on at least one of the first portion and the second portion.

The fastening assembly may include at least one spring assembly, and the supplemental fastening assembly may include at least one supplemental spring assembly.

In accordance with present invention each of the first portion, the second portion and the at least one supplemental spring assembly may extend substantially parallel to the vessel wall.

The fastening assembly may a plurality of entwined coil springs.

The supplemental fastening assembly may include a first supplemental spring assembly connected to the first portion of the fastening assembly and a second supplemental spring assembly connected to the second portion of the fastening assembly. The fastener may further include an assembly for connecting at least a portion of the at least one supplemental spring assembly to the spring assembly.

The fastener has a first orientation for inserting the fastener through the vessel wall and the surgical component, and a second orientation when the fastener is in a secured position. The spring assembly and the at least one supplemental spring assembly may be aligned along a longitudinal axis when the fastener is in the first orientation. The spring assembly and the at least one supplemental spring assembly are displaced with respect to one another from the longitudinal axis when the fastener is in the second orientation.

The fastener is in tension when in the first orientation and relaxed when in the second orientation, the fastener further includes a control assembly for controlling the compression of the fastener in the first orientation. The spring assembly and the at least one supplemental spring assembly may be coil springs having a plurality of individual coils therein. The control assembly may be located between a plurality of the individual coils.

The control assembly may include a suture fiber or material disposed between the plurality of the individual coils. The suture material may be formed from a dissolvable material, such that the suture material dissolves after the fastener is in its second orientation.

The control assembly may include a dissolvable material formed on the fastener assembly and the supplemental fastener assembly.

The present invention is also directed to a fastener for use during a surgical procedure for securing a surgical component to a vessel wall. The fastener includes a flexible fastening assembly for securing the surgical component to the vessel wall under a compressive force. The fastening assembly has a first portion located on one side of the surgical component and the vessel wall, a second portion located on another side of the surgical component and the vessel wall, and an intermediate portion connecting to the first portion and the second portion, the intermediate portion extending through the vessel wall and the surgical component. The first portion, second portion and the intermediate portion act to apply a compressive force to the surgical component and the vessel wall to secure the surgical component to the vessel wall. The fastening assembly has a first orientation for inserting the fastening assembly through the vessel wall and the surgical component, and a second orientation when the fastening assembly applies the compressive force to the surgical component and the vessel wall. The fastening assembly may be in tension when in the first orientation. The fastener further includes a control assembly for controlling the compression of the fastening assembly in the first orientation.

The present invention is also directed to an attachment assembly for securing a graft to repair a vessel having an aneurysm therein. The vessel has a proximal neck or end and a distal neck or end. The graft has a proximal end and a distal end. The attachment assembly comprises attachment means for securing the distal end of the graft to the distal end of the vessel. The attachment assembly also comprises graft attachment means for securing the distal end of the graft to the attachment means. The attachment means permits expansion of the vessel necks and/or ends without negatively impacting the connection between the graft and the vessel wall. The attachment assembly may comprise a radially extending cuff. The attachment means may comprise at least one graft attachment tube for receiving the distal end of the graft. The attachment assembly is preferably formed from a flexible material.

The present invention is also directed to a repair graft assembly for repairing a vessel having an aneurysm therein. The repair graft assembly comprises a graft assembly for creating a passageway within the vessel and thereby reinforcing it. The graft assembly has a proximal end and a distal end. The repair graft assembly also comprises an attachment

assembly. The attachment assembly comprises attachment means for securing the distal end of the graft to the distal end of the vessel. The attachment assembly also comprises graft attachment means for securing the distal end of the graft to the attachment means. The attachment means permits expansion of the vessel without negatively impacting the connection between the distal end of the graft and the vessel. The attachment assembly may comprise a radially extending cuff. The attachment means may comprise at least one graft attachment tube for receiving the distal end of the graft. The repair graft assembly is preferably formed from a flexible material. The attachment means of the repair graft assembly preferably comprises at least one graft attachment tube for receiving the distal end of the graft assembly.

The repair graft assembly comprises proximal attachment means for securing the proximal end of the graft to the proximal neck or end of the vessel. The proximal attachment means comprises a radially extending cuff.

The present invention is also directed to a visualization apparatus for viewing the interior of a vessel prior to, during and following a surgical procedure. The visualization apparatus comprises a housing and image creating means for creating an image of the interior of the vessel from within the vessel. The image creating means is located within the housing. The image creating means comprises illumination means for illuminating an area within the vessel for viewing by a user. The image creating means also comprises diverting means for temporarily diverting blood away from the viewing area. The image creating means also comprises optical viewing means for viewing the area within the vessel.

The illumination means may comprise at least one optical fiber for illuminating the area within the vessel.

The visualization means comprises means for supplying a fluid to the area to direct the flow of blood away from the viewing area, and return means for draining the fluid from the area to permit the return of blood.

The optical viewing means comprises an optical fiber. The optical viewing means may alternatively comprise scanning means for scanning an area of the vessel for creating a

non optical image of the area. The scanning means may produce an ultrasound image. The scanning means may comprise a scanning catheter.

The present invention is also directed to a penetration apparatus for use in creating a plurality of treatment specific holes in the sometimes calcified vessel wall to aid in the attachment of a graft. The penetration apparatus comprises a housing, and penetration means
5 for use in creating a plurality of treatment specific holes in the sometimes calcified vessel wall. The penetration means is located within the housing. The penetration means may comprise a laser. The laser may be an acousto optical laser or a Holmium-Yag laser. Alternatively, the penetration means may comprise a piezoelectric penetrating device. The penetration apparatus may also comprise insertion means for inserting a fastener through the
10 opening in the vessel to secure a surgical component (e.g., graft and prosthesis) to the vessel. The penetration apparatus may also comprise secondary penetration means for forming at least one opening adjacent the opening in the sometimes calcified vessel wall. The secondary penetration means may comprise a laser or piezoelectric device. The secondary penetration means stabilizes the penetration apparatus as the insertion means inserts a fastener in the
15 opening. The penetration apparatus may further comprise visual tracking means for identifying the location of the penetration apparatus within the vessel.

The present invention is also directed to repair apparatus for repairing a vessel during a surgical procedure. The apparatus comprises a housing and at least one of a penetration
20 apparatus for use in forming an opening in a vessel having a calcified portion and a visualization apparatus for viewing an interior of a vessel during a surgical procedure. The penetration apparatus comprises a penetration housing, and penetration means for forming treatment specific holes in the sometimes calcified vessel wall. The visualization apparatus comprises a visualization housing, and image creating means for creating an image of the
25 interior of the vessel from within the vessel.

The present invention is also directed to a fastener for use in a surgical procedure for securing a surgical component to a vessel. The fastener comprises fastening means for securing the surgical component to the vessel under a compressive force. The fastening means is either a wire fabrication or a coil spring fabrication.

The present invention is also directed to an introducer sheath device for use during a surgical procedure for introducing surgical components into a vessel. The introducer sheath device comprises a housing having a passageway that permits the passage of the surgical components therein. The introducer sheath device also comprises sealing means at the proximal end for preventing the loss of blood from the vessel during the insertion and subsequent removal of surgical components during the surgical procedure. The sealing means comprises a sealing cavity. The sealing cavity is filled with a sealing material, which forms a seal around the surgical components as they are inserted and removed from the introducer sheath device during the surgical procedure. The introducer sheath device further comprises positioning means for maintaining the position of the introducer sheath device within the vessel. The positioning means preferably comprises an inflatable cuff positioned at the distal end of the introducer sheath device.

Brief Description of the Drawings

The invention will now be described in conjunction with the following drawings in which like reference numerals designate like elements and wherein:

Fig. 1 is a perspective view of a prosthetic bifurcated tube graft and bifurcated cuff according to a preferred embodiment of the present invention;

Fig. 2 is a perspective view of a prosthetic bifurcated tube graft and bifurcated cuff according to another embodiment of the present invention;

Fig. 3 is a perspective view of the prosthetic bifurcated tube graft and bifurcated cuff of Fig. 1 secured within the abdominal aorta;

Fig. 4 is a perspective view of the prosthetic bifurcated tube graft and bifurcated cuff of Fig. 2 secured within the abdominal aorta;

Fig. 5 is a perspective view of a prosthetic tube graft and cuff according to another embodiment of the present invention;

Fig. 6 is a perspective view of the prosthetic tube graft and cuff of Fig. 5 secured within the abdominal aorta;

Fig. 7 is a perspective view of the connection between the prosthetic tube graft and the cuff;

Fig. 8 is a side view of the prosthetic tube graft of Fig. 6 secured to a secondary cuff;

Fig. 9 is an exploded view of the connection between the prosthetic tube graft and secondary cuff as shown in Fig. 8;

5 Fig. 10 is a perspective view of attachment cuffs according to another embodiment of the present invention;

Fig. 11 is a perspective view of the flexible attachment cuff according to embodiments of the present invention;

Fig. 12 is a perspective view of the attachment cuffs of Fig. 10 having a prosthetic tube graft secured between the attachment cuffs;

10 Fig. 13 is a perspective view of an IntraVascular Endoscopy (I'VE) based repair system according to an embodiment of the present invention containing an embodiment of a visualization device according to the present invention;

Fig. 14 is an end view of the IntraVascular Endoscopy (I'VE) based repair system according to the embodiment of Fig. 13;

15 Fig. 15 is an end view of the visualization device depicted in Fig. 13;

Fig. 16 is another perspective view of the IntraVascular Endoscopy (I'VE) based repair system illustrating the guide wire and articulation cables exiting the housing of the repair system;

20 Fig. 17 is a perspective view of an IntraVascular Endoscopy (I'VE) based repair system according to an embodiment of the present invention containing an embodiment of a penetration device according to the present invention and an embodiment of a fastener cartridge according to the present invention;

25 Fig. 18 is a perspective view of an I'VE based repair system according to another embodiment of the present invention containing a penetration device and fastener cartridge according to the present invention;

Fig. 19 is a perspective view of an I'VE based repair system according to the embodiment of Fig. 18 containing a penetration device and fastener cartridge according to another embodiment of the present invention;

Fig. 20 is a perspective view of an I'VE based repair system according to another embodiment of the present invention containing a penetration device and fastener cartridge according to the present invention;

5 Fig. 21 is an end view of the penetration device according to an embodiment of the present invention;

Fig. 22 is an end view of the penetration device according to another embodiment of the present invention;

Fig. 23 is an end view of the fastener cartridge according to the embodiment of Fig. 17;

10 Fig. 24 is a perspective view of an advancing mechanism of a penetration device according to an embodiment of the present invention;

Fig. 25 is a schematic view of another advancing mechanism of a penetration device and fastener cartridge according to another embodiment of the present invention;

15 Figs. 26 and 27 are perspective views of an IntraVascular UltraSound (IVUS) based repair apparatus according to another embodiment of the present invention containing a visualization device and a penetration device;

Fig. 28 is a cross sectional view of a housing according to an embodiment of the present invention;

Fig. 29 is an end view of a penetration device depicted in Fig. 26;

20 Figs. 30 and 31 are perspective views of a wire fastener for securing the cuff detail of a surgical cuff to a vessel wall according to an embodiment of the present invention;

Figs. 32 and 33 are perspective views of a wire fastener according to another embodiment of the present invention for securing the cuff detail of a surgical cuff to a vessel wall;

25 Figs. 34 and 35 are perspective views of a wire fastener according to another embodiment of the present invention for securing the cuff detail of a surgical cuff to a vessel wall;

Figs. 36, 37, 38, 39, 40 and 41 are perspective views of a fastener according to another embodiment of the present invention for securing the cuff to a vessel wall;

Fig. 42 is a schematic view of an embodiment of the penetration device according to the present invention having fasteners, as shown in Figs. 34, 37, 38 and 39 stored thereon;

Fig. 43 is a schematic view of another embodiment of the penetration device according to the present invention having fasteners, as shown in Figs. 36, 37, 38 and 39 stored therein;

Figs. 44 and 45 are perspective views illustrating the fastener attachment of the cuff detail to the vessel wall using a fastener as shown in Figs. 34 and 35 according to an embodiment of the present invention;

Fig. 46 is a perspective view of another embodiment of an IntraVascular Endoscopy (I'VE) based repair system according to another embodiment of the present invention;

Fig. 47 is a perspective view on an introducer sheath device according to the present invention;

Fig. 48 is a cross sectional view of a seal assembly for the introducer sheath device according to an embodiment of the present invention.

Figs. 49, 50, and 51 are perspective views of a fastener according to another embodiment of the present invention.

Figs. 52 and 53 are perspective views of a fastener according to another embodiment of the present invention for securing the cuff to a vessel wall;

Fig. 54 is a cross sectional view of a seal assembly for the introducer sheath device according to an embodiment of the present invention;

Fig. 55 is a perspective view of the introducer sheath device and seal assembly for the present invention;

Figs. 56, 57 and 58 are perspective views of a fastener according to another embodiment of the present invention; and

Fig. 59 is a perspective view of a fastener according to another embodiment of the present invention.

Detailed Description of Preferred Embodiments

The following descriptions of the preferred embodiments of the present invention are described, for purpose of example, in connection with the repair of an abdominal aortic

aneurysm. The inventors of the present subject matter contemplate that the embodiments described herein are capable of use in the repair of other vessels and in other procedures. Thus, it is intended that the present invention cover the modifications and variations of the invention, provided they come within the scope of the appended claims and their equivalents.

Repair Graft

Reference will now be made in detail to preferred embodiments of grafts according to the present invention for repair of abdominal aortic aneurysms, an example of which is illustrated in Figs. 1-11.

Figs. 1 and 3 depict a preferred embodiment of the repair graft assembly of the present invention directed to a proximal graft assembly **10** and distal graft assembly **20** for repair of a vessel **1**. The proximal graft assembly **10** and distal graft assembly **20** are secured to a wall **2** of the vessel **1** to exclude the aneurysm from the circulatory system of the patient. In the preferred embodiment of the present invention, the proximal graft assembly **10** is a bifurcated tube graft.

The distal graft assembly **20** preferably comprises an attachment cuff **21**. The attachment cuff **21** is sized to secure the distal graft assembly **20** to the wall **2** of the vessel **1** at the distal end of the vessel **1**. The distal graft assembly **20** also comprises at least one graft attachment leg, tube or branch **22**. The attachment cuff **21** is secured to the wall **2** of the vessel **1** out to the adventitia using a suitable fastener, described in detail below.

The distal graft assembly **20** is positioned within the distal end of the vessel **1**, as shown in Fig. 1 using a guide wire, not shown, that extends between and through both common iliacs. The attachment cuff **21** is then secured to distal end of the vessel **1** out to the adventitia using a repair apparatus, described below. After the attachment cuff **21** is firmly secured to the wall **2**, attachment tubes **22** are invaginated to the position shown in Fig. 3. A proximal graft assembly **10** is then secured to the attachment legs **22** using suitable connectors, such as, a self-expanding stent **30**, as shown in Fig. 7.

The bifurcated proximal graft assembly **10** comprises a pair of tubular legs **11**. The tubular legs **11** are sized to be received within/without the graft attachment tubes **22**. The bifurcated proximal graft assembly **10** may also comprise an attachment cuff **12** for

attachment to the wall 2 of the vessel 1. The attachment cuff 12 has a similar structure to the attachment cuff 21 of attachment device 20. The tubular legs 11 are invaginated following the process of securing the attachment cuff 12 to the wall 2. The attachment legs 22 may be positioned within the tubular legs 11, as shown in Fig. 3. Alternatively, the tubular legs 11 may be positioned within the attachment legs 22, as shown in the embodiment of Fig. 6.

It is also contemplated that the distal graft assembly 20 may be used with a standard tube graft 3, as shown in Fig. 2 and 4. In this variation, the tube graft 3 is secured to the wall 2 of the vessel 1 while in an inverted position, as shown in Fig. 2 using fasteners, described below, and a self-expanding stent 30, if desired. The tube graft 3 is then invaginated and secured to the distal graft assembly 20, as described above. The benefit of the invagination of the graft 3 is that the fasteners securing the graft 3 to the vessel 1 are not in direct contact with the blood within the vessel 1. This will reduce the possible build up of thrombus at the point of attachment and thereafter the creation of emboli.

The proximal graft assembly 10 and distal graft assembly 20 will enable the creation of a cross sectional area ratio between the common iliacs and the distal aorta that exists only at childhood. The ratio may be 1.1 to 1.0. This ratio minimizes the reflected wave that is instrumental in the creation of plaque deposits at the distal bifurcation.

Figs. 5 and 6 depict another embodiment of a repair graft for repair of an abdominal aortic aneurysm 1 according to the present invention. The proximal graft assembly 100 is secured to a wall 2 of the abdominal aorta to exclude the aneurysm 1 from the circulatory system of the patient. The proximal graft assembly 100 is used in connection with the distal graft assembly 20, described above. In this embodiment, the distal graft assembly 20 comprises a single attachment leg or tube 22. The proximal graft assembly 100 comprises a tube graft assembly 110 for forming a passageway within the vessel 1.

The radially extending attachment cuff 121 provides a greater surface area for securing the proximal graft assembly 100 to the wall 2. Additionally, the radially extending portion 121 is flexible, which permits some positioning adjustment of the proximal graft assembly 100 in the event the size of the passageway within the abdominal aorta changes after the surgical procedure. Fig. 11 illustrates the flexibility of the attachment cuff 21 which

is similar to attachment cuff 121. Like the embodiment of Figs. 1 and 3, the proximal graft assembly 100 is secured to the vessel wall 2 in an invaginated manner, as shown in Fig. 5. After the attachment cuff 121 is secured to the vessel wall 2, the proximal graft assembly 100 is invaginated to the position shown in Fig. 6. The tubular leg assembly 110 is then secured to the distal graft assembly 20, as shown in Fig. 7. In a preferred embodiment, a self-expanding stent 30 is used to secure it to the attachment leg 22 of the distal graft assembly 20. The self-expanding stent 30 applies radial pressure against an inner surface of tube graft assembly 110 to secure the tube graft assembly 110 to the distal graft assembly 20.

The self-expanding stent 30 is a preferred method of securing the proximal tube assemblies 10 or 100 to the distal graft assembly 20. However, it will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing from the scope or spirit of the invention. For example, surgical staples, sutures, adhesives or other methods may be used to secure the proximal graft assembly 10 to the distal graft assembly 20. Thus, it is intended that the present invention cover the modifications and variations of the invention, provided they fall within the scope of the appended claims and their equivalents.

As described above in connection with Figs. 2 and 4, it is also contemplated that the distal graft assembly 20 may be used with a standard tube graft, not shown. The tube graft will also be secured to the wall 2 of the vessel 1 while in a cephalad position using either fastener devices, described below, or a self-expanding stent 30. The tube graft is then invaginated and secured to the distal graft assembly 20, as described above.

Figs. 8 and 9 depict a proximal attachment assembly 150 according to the present invention for securing the proximal graft assembly 10 or 100 to the proximal end of the vessel 1. It is preferred that the proximal attachment assembly 150 be used in connection with securing the proximal graft assemblies 10 or 100 to the vessel wall 2 according to preferred embodiments of the present invention as shown, for example, in Figs. 5, 6, 8 and 9. The proximal attachment assembly 150 comprises a cuff attachment portion 151 and a vessel attachment portion 152. The attachment cuff 12 or 121 is secured to the cuff attachment portion 151, by sewing, for example. The vessel attachment portion 151 is then

secured to the vessel **1** using, for example, a fastener or a self-expanding stent **30** and fasteners, if necessary. Alternatively, the proximal attachment assembly **150** may be invaginated and secured to the vessel **1** in the manner described above in connection with Figs. 2 and 4. The cuff attachment portion **151** and the attachment cuff **12** or **121** interact in
5 a manner such that the proximal graft assembly **10** or **100** are not impacted by the expansion of the neck of vessel **1** after the surgical procedure.

Another embodiment of the repair grafts according to the present invention are disclosed in Figs. 10 and 12. The embodiment of Figs. 10 and 12 utilizes a pair of distal graft assemblies **20**, which are secured at the proximal and distal ends of the vessel. A proximal
10 graft assembly **1000**, which forms a passageway within the vessel **1** interconnects the distal graft assemblies **20**. As described above, the proximal graft assembly **1000** is secured to the attachment legs **22** of the distal graft assemblies **20** using a self-expanding stent **30** or other suitable fastening means. The attachment legs **22** may be inserted in the proximal graft assembly **1000**. Alternatively, the proximal graft assembly **1000** may be inserted in the
15 attachment legs **22**, as shown in Fig. 12.

The above described repair grafts facilitates repair of a vessel in a manner that is neither profile nor dimension dependent. This is especially helpful in view of the fact that the necks of the post-surgical aorta typically increases in size for approximately twelve months. The above-described repair grafts accommodate such expansion without allowing
20 leaks or graft migration. The attachment cuffs are capable of accommodating dimensional changes in the necks of the abdominal aorta. Furthermore, the use of the distal graft assembly **20** permits distal attachment removing the need for iliac/femoral attachment.

In accordance with the present invention, detailing and assembly of the graft within the abdominal aorta creates a situation in which the fasteners are positioned outside the blood
25 flow and are therefore not a focal point for thrombus creation. Both distal and proximal bifurcated grafts in accordance with the present invention may be strategically marked with radiopaque materials to enable their visual tracking and correct positioning prior to fixation within the aorta. A frieze/band of platinum oxide is vacuum deposited, photo deposited, silkscreened, or otherwise adhered to the graft material at the location of the tube end

(proximal graft), tube end/halo transition (distal graft), and at the halo perimeter. Other noble metals such as gold, molybdenum and titanium may also be successfully used as marking material. Radiopaque wires or metal fragments have been woven or otherwise incorporated into grafts -- the coating methods listed above, have not. The ring details previously
5 discussed titanium or polymeric (suitably impregnated) are also radiopaque.

In the above described embodiments, the proximal graft assemblies **10**, **100** and **1000**, distal graft assembly, and proximal attachment assembly **150** are preferably formed from a twill weave, non-crimped polyester, Gore-Tex® or equivalent biocompatible material. It will be apparent to those skilled in the art that various modifications and variations can be made
10 in the construction and configuration of the present invention without departing from the scope or spirit of the invention. For example, in the embodiments mentioned above, various other suitable materials such as, Dacron®, and other biocompatible graft materials may be used to form the repair grafts. Thus, it is intended that the present invention cover the modifications and variations of the invention, provided they fall within the scope of the
15 appended claims and their equivalents.

The attachment cuffs may include a ring located at the perimeter. This ring may comprise a metal spring wound into holes cut in the cuff of a polymeric spring which is molded directly to the cuff. The ring serves to keep the cuff fully expanded during the attachment process of the graft to the vessel wall. The ring has no negative impact on the
20 insertion process, described below.

Similar to other graft procedures, the proximal graft assemblies **10**, **100**, or **1000** according to the present invention require attachment to the wall **2** of the vessel. Often, it is necessary to attach the distal end of the graft into material which is routinely calcified and therefore difficult to penetrate. When paired with the absence of a distal neck in the vessel,
25 the presence of the plaque has forced others to promote the use of a bifurcated graft in which the graft limbs are fastened by stents within the common iliac or femoral arteries. This procedure may potentially damage the femoral arteries. Furthermore, the presence of a graft and stent within the iliac or femoral arteries potentially restricts the flow of blood within the

vessels. This is unnecessary when utilizing the repair grafts according to the present invention.

IntraVascular Endoscopy (I'VE) Based Repair System

Reference will now be made in detail to preferred embodiments of an apparatus
5 according to the present invention for facilitating the repair of abdominal aortic aneurysms using above described grafts. An example of an intravascular endoscopy based system is depicted in Figs. 13-22.

The repair apparatus **5** comprises a housing **200** for alternately receiving a
visualization apparatus **6** and a penetration apparatus **7**, as shown in Fig. 20. It, however, is
10 contemplated by the inventors of the present invention that the visualization apparatus **6** and
penetration apparatus **7** may be combined into a single assembly within the repair apparatus
5. The housing **200** has a hollow construction, as illustrated in Fig. 14, which permits
insertion of the visualization apparatus **6** or the penetration apparatus **7**, described in detail
below. The housing **200** is divided into two primary portions: static housing portion **210**; and
15 flexible housing portion **220**. The housing **200** has a sufficient length such that it extends
from the repair site within the vessel **1** through the appropriate or chosen artery to a point
outside the patient.

The housing **200** has a hollow interior **211** to permit passage of one of the
interchangeable apparatus **6** and **7**. An inner surface of the hollow interior **211** comprises
20 rotation prevention means **212** for properly orienting the interchangeable apparatus **6** and **7**
within the housing **200**. In a preferred embodiment, the rotation prevention means **212** is a
ridge, as shown in Fig. 14, that extends along the inner surface of the hollow interior **211**.

It, however, will be apparent to those skilled in the art that various modifications and
variations can be made in the construction and configuration of the present invention without
25 departing from the scope or spirit of the invention. For example, the rotation prevention
means **211** mentioned above, may be located at different radial positions within the housing
and may also be a ridge, a groove, a plurality of grooves, or other devices capable of
preventing rotation of the interchangeable apparatus **6** and **7** within the housing **200**. Thus,

it is intended that the present invention cover the modifications and variations of the invention, provided they fall within the scope of the appended claims and their equivalents.

Positioned within the housing **200** is an apparatus guide means **214** for guiding the repair apparatus **5**, as shown in Figs. 13 and 17, within the vessel **1** during use. The guide means **214** preferably is a passageway or lumen extending within the housing wall through the static portion **210**. A guiding means **160** cooperates with guide means **214** to guide the apparatus **5** during use. The guiding means **160** is preferably a guide wire which is capable of extending from the femoral artery to the axillary artery. In a preferred embodiment, the guide wire **160** is a filament (e.g., stainless steel, titanium or a Kevlar®). It, however, will be apparent to those skilled in the art that various other materials having similar properties of physical integrity, high strength, flexibility, and minimal thermal expansion may be used to form the guide wire **160**. The guide wire **160** projects from the flexible housing portion **220** through an aperture **226** in the housing **200**, as shown in Fig. 14.

Housing **200** also comprises an apparatus manipulation means **215** to aid in manipulating and orienting the apparatus **5** within the vessel **1** during the repair operation. The manipulation means **215** preferably comprises at least one passageway extending within the housing wall through the static housing portion **210** and terminating in the flexible housing portion **220**. A manipulating means **170** cooperates with manipulation means **215** to guide the apparatus **5** during use. The manipulating means **170** is preferably comprises at least one guide wire that is capable of extending from outside the patient through the housing **200**. The guide wires **170** extend through the manipulating means **215**. In a preferred embodiment, the guide wires **170** are filaments (e.g., stainless steel, titanium or a Kevlar®). It, however, will be apparent to those skilled in the art that various other materials having similar properties of physical integrity, high strength and flexibility may be used to form the guide wires **170**.

The guide wires of the manipulating means **170** terminate within the flexible housing portion **220**. Operation of the manipulating means **170** results in the articulation of an end portion of the flexible housing portion **220**. The guide wires **170** maintain the flexible housing portion **220** in an articulated position, as shown in Figs 13 and 16, such that the

visualization apparatus 6 and the penetration apparatus 7 can be interchanged without altering the orientation of the repair apparatus 5 with respect to the surgical site.

The wall of the static housing portion 210 comprises an outer surface formed from silicone and an inner surface formed from Teflon®. It, however, will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing from the scope or spirit of the invention. For example, the housing wall may be formed from a suitable polymer (e.g., Pebax®) or other material having similar properties including, but not limited to biocompatibility, flexural strength, low coefficient of friction. Thus, it is intended that the present invention cover the modifications and variations of the invention, provided they fall within the scope of the appended claims and their equivalents.

The flexible housing portion 220 may be formed in a manner similar to static housing portion 210. For example, the housing may comprise an outer surface formed from silicon and an inner surface formed from Teflon®. It, however, will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing from the scope or spirit of the invention. For example, the lining may be formed from a suitable polymer or other material having similar properties including, but not limited to biocompatibility, flexural strength, low coefficient of friction. Alternatively, the flexible housing portion 220 may comprise a coiled metallic spring outer casing 224 that surrounds a lining. The lining may be formed from Teflon®. The coiled metallic spring outer casing 224 may be formed from a biocompatible stainless steel or titanium. Furthermore, the spring outer casing 224 may be formed from other suitable spring materials. It is not necessary that the outer spring casing 224 extend along the entire length of the flexible housing portion 220. Rather, the outer spring casing 224 may be positioned along the portion of the flexible housing portion 220 that is subject to bending. However, it is contemplated that an outer spring casing that extends along the entire length of the flexible housing portion 220 be within the scope of the present invention.

The flexible housing portion **220** and the static housing portion **210** are manufactured as separate components. It, however, will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing from the scope or spirit of the invention. For example, the static housing portion **210** and the flexible housing portion **220** may be formed as a single component. In a preferred embodiment, the static housing portion **210** is permanently secured to the flexible housing portion **220**. However, it is contemplated that the housing portions **210** and **220** may also be removably attached.

Figs. 18 and 19 illustrates another repair apparatus **500** for alternatively receiving a visualization apparatus **6** and a penetration apparatus **7** according to another embodiment of the present invention. The repair apparatus **500** comprises a housing **2000** for alternatively receiving a visualization apparatus **6** and a penetration apparatus **7**. The housing **2000** is flexible and has a sufficient length such that it extends from the repair site within the vessel **1** through the appropriate artery to a point outside the patient.

The housing **2000** is hollow, as described above in connection with housing **200**, to permit passage of one of the interchangeable apparatus **6** or **7**. The housing **2000** includes at least one guide means **2140** positioned at the exterior of the housing **2000** for guiding the repair apparatus **500** within the vessel **1** during use. The guide means **2140** preferably is a passageway extending along the exterior of the housing wall to a point adjacent the distal end **2001** of the housing **2000**.

Guide wires **160** extend within the guide means **2140**. The guide wires **160** extend from the end of guide means **2140** and are secured to the distal end **2001** of the housing **2000**, as shown in Figs. 18 and 19. Adjustment of the guide wires **160** manipulates the position of the repair apparatus **500** within the vessel **1**. The above described arrangement permits a wide range of articulation of the repair apparatus **500** within the vessel **1**.

An additional guide wire **161** is secured to the distal end **2001** of the housing **2000**. The guide wire **161** extends through the vessel **1** and appropriate artery to permit the positional adjustment of the repair apparatus **500** within the vessel.

Fig. 20 illustrates another repair apparatus **5000** for alternatively receiving a visualization apparatus **6** and a penetration apparatus **7** according to another embodiment of the present invention. The repair apparatus **5000** comprises a flexible hollow housing **2010** and has a sufficient length such that it extends from the repair site within the vessel **1** through the appropriate artery to a point outside.

The housing **2010** includes at least one guide wire **162** extending along the exterior of the housing **2010**, as shown in Fig. 20. The housing **2010** includes an inflatable portion **2011**, located adjacent the distal end **2001**. Inflation of the inflatable portion **2011** permits articulation of the repair apparatus **5000** within the vessel **1**. A passageway, not shown, extends within the housing **2010** to permit inflation of the inflatable portion **2011** with a suitable fluid, such as, saline or suitable liquid polymers or air. An additional guide wire **161** is secured to the distal end **2001** of the housing **2010**. The guide wire **161** extends through the vessel **1** and appropriate artery to permit the positional adjustment of the repair apparatus within the vessel.

The overall dimensions of the repair apparatus **5** allows axillary access. This previously was not possible. In this regard, the repair apparatus used in connection with the visualization apparatus **6** or penetration apparatus **7** is capable of being used in other surgical procedures not previously contemplated. The apparatus size permits insertion through an introducer sheath device **900**, described below. The apparatus **5** may also be introduced into a vessel percutaneously. This procedure is less invasive and/or intrusive when compared to other repair surgical procedures.

IntraVascular Endoscopy (I'VE) Visualization Apparatus

Reference will now be made in detail to preferred embodiments of the interchangeable apparatus **6** and **7** for use with the repair apparatus **5** according to the present invention for facilitating the repair of abdominal aortic aneurysms. The visualization apparatus **6** will now be described in connection with Figs. 13 and 15.

A visualization apparatus **6** may be inserted within the repair apparatus **5** to illuminate and permit real time direct viewing of the abdominal aorta to aid the diagnosis and repair of the aneurysm. The visualization apparatus **6** is an intravascular endoscope based system

that comprises a housing 300 for housing various illuminating and viewing components. The housing 300 is preferably formed as a conduit that is sized to slide within housing 200. In a preferred embodiment, the housing 300 is an extrusion of silicon, Teflon® or polymer or other material having similar properties.

5 The housing 300 extends through the hollow interior 211 of the housing 200. The housing 300 may comprise orientation means 310 for orienting the visualization apparatus 6 within the housing 200. The orientation means 310 cooperates with rotation prevention means 212. In a preferred embodiment, the orientation means 310 is a channel that extends
10 along an outer surface of the housing 300. It, however, will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing from the scope or spirit of the invention. For example, the orientation means 310 mentioned above may be located at different radial positions within the housing 300. The orientation means 310, may be a ridge, a groove, a plurality of grooves, or other devices that are complementary with the rotation
15 prevention means 212 to prevent rotation of the visualization apparatus 6 within the housing 200.

As shown in Fig. 15, housing 300 comprises a plurality of passageways 311, 312, 313, 314, and 315 formed therein. The passageways 311, 312, 313, 314, and 315 extend along the entire length of the housing 300. Central passageway 311 is provided for the
20 passage of optical viewing means 320 for viewing an abdominal aorta. In a preferred embodiment, the optical viewing means 320 is a fiber optic system. The system incorporates a fiber optic bundle. It, however, will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing from the scope or spirit of the invention. For example, the
25 optical viewing means 320 mentioned above, may be any flexible optical system that is sized for use in surgical applications. The optical viewing means 320 permits real time direct viewing of the area of repair in the vessel 1. The optical viewing means 320 may be connected to a video camera and monitor, not shown, that permits the surgeon to view the repair area. The images may be stored and recalled as desired by using either a video printer

or video cassette recorder. The penetration apparatus 7 will be located at the same position as the visualization apparatus 6. The penetration apparatus 7 incorporates a radio opaque marker that will indicate the precise position of the penetration apparatus 7 on the monitor. This allows the surgeon to monitor and track the adjustments of the repair apparatus 5.

5 Peripheral illumination passageways 312 and 313 are provided for the passage of illuminating means 330 for illuminating the abdominal aorta for viewing by the optical viewing means 320. In a preferred embodiment, the illuminating means 330 is a fiber optic system including a fiber optic bundle. It, however, will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration
10 of the present invention without departing from the scope or spirit of the invention. For example, the illuminating means 330 mentioned above, may be any system that is sized for use in surgical applications and capable of illumination within the aorta. Although a pair of passageways are illustrated, it is contemplated that a single illumination passageway will provide sufficient illumination. Additionally, more than two passageways may also be
15 provided.

 Peripheral fluid inflow passageway 314 and peripheral fluid outflow passageway 315 are provided for the passage of fluid lens media to and from the visualization tip 340. The peripheral fluid inflow passageway 314 supplies a stream of optically clear fluid lens media from the visualization tip 340 in the area in front of the optical viewing means 320. A control
20 means, not shown, may be incorporated into passageway 314 to control the flow volume and velocity of the fluid lens media to the visualization tip 340. The control means may be a valve or other suitable flow control devices. The control means controls the optically clear fluid lens media such that blood within the aortic cavity and the fluid lens media are pressure balanced. As a result, blood that is typically within the aorta is temporarily diverted away
25 by the fluid lens media to a point adjacent the area of the wall 2 to be viewed by the optical viewing means 320. The infusion of fluid lens media will dilute blood to an appropriate transparency in the immediate surgical site to exclude blood between the visualization tip 340 and the surgical site on the wall 2. This permits the surgeon to clearly view the wall 2 through the optical viewing means 320. In a preferred embodiment, the fluid lens is a

transparent fluid to permit viewing of the wall 2. The fluid lens media may be a saline solution. It is preferred that the solution be used for a single application (i.e., it is not reused). Other media, such as CO₂ gas and Green Cross liquid fluorocarbon are contemplated to be within the scope of the present invention. The peripheral fluid outflow passageway 315 acts as a return duct for the fluid lens media within the aorta. Alternatively, the fluid lens media may then be filtered using an appropriate filtering means and recirculated using a pumping means through the peripheral fluid inflow passageway 314.

In a preferred embodiment, it is contemplated that the visualization apparatus 6 be used in combination with the introducer sheath devices 900, described below. The introducer sheath devices 900 and in particular the positioning assemblies 920 permit the isolation of a portion of the vessel during the repair procedure. Specifically, the positioning assemblies 920 within the common iliacs and femoral artery permit the control of blood within the vessel. With this arrangement, it is then possible to more readily divert blood away from a viewing area with the flow of fluid lens media from the fluid inflow passageway 314.

A visualization tip 340 is securely mounted to the end of housing 300 in a fluid tight manner. The tip 340 may be snap fitted or permanently mounted to the housing 300. It, however, will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing from the scope or spirit of the invention. For example, the visualization tip 340 mentioned above, may be secured to the housing 300 by means other than the above described snap and permanent fittings. The visualization tip 340 may be formed by injection molding or other suitable manufacturing methods in silicone or similar polymer.

The visualization tip 340 comprises apertures 341, 342, 343, 344, and 345 that correspond to passageways 311, 312, 313, 314, and 315, respectively. Aperture 341 contains a lens positioned therein to facilitate viewing of the wall 2 with the optical viewing means 320. Apertures 342 and 343 may include windows therein whereby light from the illuminating means 330 passes through the windows to illuminate the wall 2, although it is not necessary. Apertures 344 and 345 act as gates for the peripheral fluid inflow passageway 314 and peripheral fluid outflow passageway 315. The aperture 344 may be inwardly

tapered, such that the inside diameter of the aperture adjacent the inflow passageway **314** is greater than the diameter on the outer surface of the tip **340** to concentrate the stream of fluid lens media from the fluid inflow passageway **314**. The aperture **345** may be outwardly tapered, such that the inside diameter of the aperture adjacent the inflow passageway **315** is less than the diameter on the outer surface of the tip **340**. It is contemplated that the tip **340** is optional.

Penetration Apparatus

A penetration apparatus **7** will now be described in connection with Figs. 17-25. The penetration apparatus **7** may be inserted within the repair apparatus **5**, **500**, **5000**, as shown in Figs. 17-20, for fastening a repair graft to the vessel wall **2**. The penetration apparatus **7** comprises several components for fastening a repair graft including penetration means **420**, secondary penetration means **430**, tracking means **440** and insertion means **450**. The penetration apparatus **7** comprises housing **410** for housing the penetration means **420**, secondary penetration means **430**, tracking means **440** and insertion means **450**. In a preferred embodiment, the housing **410** has a thin walled tri-limbed profile, as shown in Figs. 19, 21, and 22. In a preferred embodiment for increased flexibility, the housing **410** is positioned within the repair apparatus **5** such that two of the three limbs of the housing **410** are spaced from the side of housing **200** containing the guide wire **160**. It, however, will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing from the scope or spirit of the invention. For example, the housing **410** mentioned above, may have more than three limbs. Alternatively, the housing **410** may be cylindrical having a plurality of inwardly projecting limbs. An alternative configuration for housing **4100** is depicted in Figs. 18 and 20. The housing **4100** comprises a central passageway **4110** containing penetration means **420**. Additional passageways **4210** and **4130** are provided for other components such as secondary penetration means, tracking means and insertion means.

The housing **410** is preferably formed from an extrusion of silicone, Teflon®, or polymer having similar properties. Housing **410** comprises a plurality of passageways **411**, **412**, **413**, and **414**, formed therein as shown in Fig. 21. An alternative arrangement is shown in Fig. 22. The passageways **411**, **412**, **413**, and **414** extend along the entire length of the

housing means **410**. Primary passageway **411** is provided for the passage of the penetration means **420**. The penetration means **420** is provided to create a treatment specific hole in the wall **2** of the abdominal aorta for securing the graft thereto with a suitable fastener device, described below. The penetration means **420** penetrates the potentially calcified vessel wall **2** to securely fasten the repair graft to the wall **2**. The penetration means **420** may be either a laser penetrating device or a piezoelectric penetrating device. It, however, is contemplated by the inventors of the present invention that other penetration means including but not limited to CO₂ penetration, micro electromechanical systems, and intraluminal suturing are considered to be within the scope of the present invention. The laser penetrating device **420** preferably is an IR fiber optic based system using laser energy to create treatment specific holes in the aorta wall **2**. The fused silica/quartz fibers that are utilized are in the 200-600 micron size range. Suitable lasers comprise but are not limited to an acousto optical laser having a wavelength of about 1.35 μm , and a Holmium-Yag laser having a wavelength of about 2.1 μm . The selected wavelength allows transition of laser energy through the fiber in the passageway **411**. The laser fiber will be in direct contact with the surgical site such that the fiber projects from the end of the housing **410**. It is contemplated that a single, or tri-pronged hole pattern will be created using penetration means **420** and secondary penetration means **430**.

The piezoelectric penetrating device preferably is a catheter based system, which utilizes acoustic vibrations to create treatment specific suture holes to aid in graft/tissue attachment. The piezoelectric penetrating device applies an "acoustic wave" effect to create holes in the graft and vessel wall. In this variation, the passageway **411** preferably contains a super elastic titanium catheter, in rod or tube form, which enables transmittance of energy through the sometimes tortuous vessels to the surgical site. The catheter will be in direct contact with the surgical site such that the catheter projects from the end of the housing **410** into the formed treatment specific hole. The secondary penetration means **430** creates one or more temporary hole(s). The piezo-electronic device preferably operates at a frequency of 20 KHz. Other frequencies, both higher and lower, are contemplated to be within the scope of the present invention. The primary penetration means **420** is coaxial with the

fastener devices such that the fastener devices may be inserted through the treatment specific hole created by the primary penetration means **420**.

Secondary passageway **412** is provided for the passage of the secondary penetration means **430**. The secondary penetration means **430** is also provided to create one or more temporary holes in the vessel wall **2**, in a manner similar to the primary penetration means **420**. Similarly, the secondary penetration means **430** may be either a laser penetrating device or a piezoelectric penetrating device, as described above in connection with the penetration means **420**. The secondary penetration means **430** serves to anchor and orient the penetration apparatus **7** while a fastener is inserted within the treatment specific hole formed by the primary penetration means **420**. After the secondary penetration means **430** is removed, the temporary holes will seal with blood that will coagulate.

Passageway **413** is provided within the housing **410** for passage of the insertion means **450**, described below. Passageway **414** is provided within the housing means **410** for passage of the tracking means **440**. In a preferred embodiment, the tracking means **440** is a radiopaque marker, which is utilized for the purpose of identifying the location of the penetration apparatus **7** within the image on the monitor. It, however, will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing from the scope or spirit of the invention. For example, the tracking means **440** mentioned above, may be a tip-tracking device or a fiber optic aiming beam.

Insertion means **450** for securing the repair graft to the wall **2** during repair of the aneurysm will be described in connection with Fig. 24. The insertion means **450** preferably comprises a mechanism that drives an individual fastener from a fastener cartridge **460**, shown in Figs. 17 and 23, into and through the treatment specific holes created by the penetration means **420** in the repair graft and wall **2**. The fastener cartridge **460** is capable of holding a plurality of fasteners such that more than one fastener may be sequentially displaced from the cartridge **460** to secure the repair graft to the abdominal aorta wall **2**. Fastener cartridge **460** is preferably detachably connected to housing **410**. The fastener cartridge **460** is a hollow housing, as shown in Fig. 23, preferably formed of injection molding HDPE or Liquid Crystal, manufactured by the RTP Co. of MN. The penetration

means 420 and 430, the tracking means 440 and the insertion means 450 are appropriately accommodated within the interior of the cartridge structure 460. The cartridge 460 is positioned about the housing 410.

The insertion means 450 illustrated in Fig. 24 comprises a driving means 451 for driving the fastener devices to secure the repair graft to the vessel wall 2. A gear 452 and fastener advancing means 453 are positioned within an opening 454 in housing 410. In a preferred embodiment, the gear 452 is a worm gear. However, other suitable gear assemblies are contemplated to be within the scope of the present invention. The gear 452 is connected to the driving means 451. The fastener advancing means 453 interacts with the gear 452 to advance a fastener device to secure the repair graft to the vessel wall 2. In a preferred embodiment, the fastener advancing means 453 is an internally geared drive plate assembly. The drive plate assembly may be capable of limited angular adjustment. Operation of the insertion means 450 is controlled by a control device, not shown, such that upon actuation by the control device, the fastener advancing means 453 is advanced to eject a fastener device from fastener cartridge 460. Alternatively, the insertion means 450 may be hand operated. The insertion means 450 is used, for example, in the embodiment illustrated in Fig. 19.

Another embodiment of the insertion means 4500 is illustrated in Fig. 25. An insertion cartridge 4510 is secured to the distal end of the repair apparatus 5. The insertion cartridge 4510 may be snap fitted to the housing 200. The insertion cartridge 4510 comprises a cavity 4511. A spring means 4520 is positioned within the cavity 4511. A fastener cartridge 460 is also located within the cavity 4511. An opening 4530 is located at one end of the insertion housing 4510. The housing 410 of the penetration apparatus 7 normally prevents the spring means 4520 from ejecting a fastener device through the opening 4530. The insertion means 4500 comprises retraction means 4540 which retracts the housing 410 away from the opening 4530 which permits the fastener to be ejected into the treatment specific hole created by the primary penetration means 420. The retraction means 4540 may be a cable that acts to retract the housing 410 away from opening 4530. The release of the retraction means 4540 causes the housing 410 to return to the position adjacent the opening 4530 to prevent the discharge of a subsequent fastener device.

IntraVascular UltraSound (IVUS) Repair System

Reference will now be made in detail to preferred embodiments of an apparatus according to the present invention for facilitating the repair of abdominal aortic aneurysms using above described repair grafts. An example of an intravascular ultrasound based system is depicted in Figs. 26-29.

The repair apparatus **50** comprises housing **800**. The housing **800** comprises a major guide wire portion **810**, a cross-section of which is shown in Fig. 28, a spacer portion **820**, and a minor guide wire portion **830**.

Positioned within the housing **800** is an apparatus guide means **214** for guiding the repair apparatus **50** within the vessel **1** during use. The guide means **214** preferably is a passageway or lumen extending the length of the housing **800** through major guide wire portion **810**, the spacer portion **820**, and the minor guide wire portion **830**. A guiding means **160** cooperates with guide means **214** to guide the apparatus **50** during use. The guiding means **160** is preferably a guide wire which is capable of extending from the femoral artery to the axillary artery. In a preferred embodiment, the guide wire **160** is a filament (e.g., stainless steel, titanium or Kevlar® cable). It, however, will be apparent to those skilled in the art that various other materials having similar properties of physical integrity, high strength, flexibility, and minimal thermal expansion may be used to form the guide wire **160**.

Housing **800** also comprises an apparatus manipulation means **215** to aid in manipulating and orienting the penetration apparatus **700** within the vessel **1** during the repair operation. The manipulation means **215** preferably comprises at least one passageway extending within the housing **810**. The manipulation means **215** mates with complimentary passageways formed in housing **710**. A manipulating means **170** cooperates with manipulation means **215** to guide the apparatus **50** during use. The manipulating means **170** is preferably comprises at least one guide wire that is capable of extending from outside the patient through the housings **810** and **710**. The guide wire **170** extends through the manipulating means **215**. In a preferred embodiment, the guide wire **170** is a super elastic metal filament. It, however, will be apparent to those skilled in the art that various other materials having similar properties of physical integrity, high strength and flexibility may be used to form the guide wire **170**.

Operation of the manipulating means 170 results in the articulation of an end portion of the housing 710. The guide wire 170 maintains the housing 710 in an articulated position. as shown in Fig. 26, during the repair operation.

The penetration apparatus 700 will now be described in connection with Figs. 26-29.

5 The penetration apparatus 700 comprises several components for fastening a repair graft including penetration means 420, secondary penetration means 430, tracking means 440, and insertion means 450. The penetration apparatus 700 comprises housing 710 for housing the penetration means 420, secondary penetration means 430, and insertion means 450. In a preferred embodiment, the housing 710 has a thin walled tri-limbed profile, as shown in Figs.

10 26, 27 and 29. It, however, will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing from the scope or spirit of the invention.

The housing 710 is preferably formed from an extrusion of silicone, Teflon®, or polymer having similar properties. Housing 710 comprises a plurality of passageways 711,

15 712, 713, 714, and 715 formed therein as shown in Fig. 29. The passageways 711, 712, 713, 714 and 715 extend along the entire length of the housing 710. Primary passageway 711 is provided for the passage of the penetration means 420. The penetration means 420 is provided to create an treatment specific hole in the wall 2 of the abdominal aorta for securing the graft thereto with a suitable fastener device. The penetration means 420 penetrates the

20 calcified portions of the wall 2 to securely fasten the repair graft to the wall 2 in the same manner as described above in connection with the endoscopic based system. The penetration means 420 may be either a laser penetrating device or a piezoelectric penetrating device.

Secondary passageway 712 is provided for the passage of the secondary penetration means 430. The secondary penetration means 430 is also provided to create one or more

25 openings in the vessel wall 2, in a manner similar to the primary penetration means 420, as described above.

Passageway 713 is provided within the housing 710 for passage of the insertion means 450. Passageway 714 is provided within the housing 710 for passage of the guide wire 170. Passageway 715 is provided for tracking means 440. The insertion means 450

30 preferably comprises a mechanism that drives an individual fastener from a fastener cartridge

470, shown in Figs. 26 and 27, into and through the treatment specific holes created by the penetration means 420 in the repair graft and wall 2. The fastener cartridge 470 is capable of holding a procedure specific quantity of fasteners such that more than one fastener device may be sequentially displaced from the cartridge 470 to secure the repair graft to the wall 2.

5 Fastener cartridge 470 is preferably detachably assembled to housing 710. The fastener cartridge 470 has a hollow housing 471, as shown in Fig. 26. The penetration means 420 and 430, and the placement/fastener means 450 are appropriately accommodated within the interior of the cartridge structure 460. The cartridge structure 470 and associated fastener device are complimentary with the spacer portion 820 of the housing 800 such that the
10 penetration apparatus 700 has a flush profile, as shown in Fig. 27.

A visualization apparatus 600 for viewing the abdominal aorta to repair the aneurysm is positioned within housing 800 adjacent the minor guide wire portion 830. The visualization apparatus 600 is an intravascular ultrasound (IVUS) based system produced, for example, by Endosonics of Rancho Cordova, CA, that comprises a housing 601 for
15 housing radial scanning components. The housing 601 may comprise a scanning window 602, however, it is not essential for the effective operation of the visualization apparatus 600. The visualization apparatus comprises scanning catheter positioned within the housing 601 such that it scans the area of the abdominal aorta. The housing 601 is an extrusion of silicon, Teflon® or polymer or other material having similar properties. The scanning catheter
20 extends through the minor guide wire portion 830 of housing 800. The scanning catheter creates an image of the repair that can be viewed on an external monitor, not shown.

The housing 800 also comprise transition portions 801 and 802 located on opposite ends of the penetration apparatus 700 to provide the repair apparatus 50 with a smooth profile, as shown in Fig. 27. This improves the movement of the repair apparatus 50 within
25 the vessel 1 and adjacent arteries.

Fasteners

Reference will now be made in detail to embodiments of a fastener device, as depicted in Figs. 30-41, 49-53 and 56-59 according to the present invention for securing the attachment device 20 to the distal end of the vessel 1. Although the fastener devices are
30 described in connection with the repair of an aneurysm in a vessel, the use of the fastener

devices in other surgical procedures as a replacement for sutures is contemplated to be within the scope of the present invention.

Figs. 30 and 31 depict a fastener **510** according to an embodiment of the present invention. The fastener **510** comprises a pair of normally splayed fastening legs **512** and **513**. The fastener **510** also comprises an anchoring portion **514**, as shown in Fig. 31. The fastener **510** is preferably formed from a wire-like material. The anchoring portion **514** may be formed from a coil of the wire-like material. The legs **512** and **513** are temporarily reoriented, as shown in Fig. 30, for storage on a fastener cartridge **460** and for enabling the attachment of the attachment device **20** to the wall **2**. As the legs **512** and **513** are inserted through the attachment device **20** and the wall **2**, the legs **512** and **513** return to a normal, as manufactured, splayed position, as shown in Fig. 31. When the fastener **510** is in a fastened position within the vessel, the anchoring portion **514** is positioned on one side of the attachment device **20** and wall **2** (intima/graft) adjacent the attachment device **20**. The splayed legs **512** and **513** are positioned on the opposite side of the attachment device **20** and wall **2** (adventia) adjacent the wall **2**. The anchoring portion **514** and splayed legs **512** and **513** apply compressive forces to the wall **2** and the attachment device **20** to securely fastening the attachment device **20** to the vessel **1**.

The fastener **510** is preferably formed from a stainless steel, such that the legs **512** and **513** return to the splayed position to secure the attachment device **20** to the wall **2**. It, however, will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing from the scope or spirit of the invention. For example, the fastener **510** may be formed from other suitable materials including but not limited to superelastic titanium, or other procedure/performance appropriate materials such as plastics having similar properties including, but not limited to biocompatibility, elasticity, and flexural strength. Thus, it is intended that the present invention cover the modifications and variations of the invention, provided they fall within the scope of the appended claims and their equivalents.

Figs. 32 and 33 depict a fastener **520** according to an another embodiment of the present invention. The fastener **520** comprises a pair of normally splayed fastening legs **522** and **523**. The fastener **520** also comprises an anchoring portion **524**. The fastener **520** is also

preferably formed from a wire-like material. The anchoring portion 524 may be formed from at least one coil of the wire-like material (i.e., a wound portion). The legs 522 and 523 are temporarily compressed, as shown in Fig. 32, for storage in a fastener cartridge 460 and for facilitating the attachment of the attachment device 20 to the wall 2. Similar to the embodiment described above in connection with Figs. 30 and 31, as the legs 522 and 523 are inserted through the attachment device 20 and the wall 2, the legs 522 and 523 return to a normally splayed position, as shown in Fig. 32. When the fastener 520 is in a fastened position within the vessel, the anchoring portion 524 is positioned on one side of the attachment device 20 and wall 2 adjacent the attachment device 20. The splayed legs 522 and 523 are positioned on another side of the attachment device 20 and wall 2 adjacent the wall 2. The anchoring portion 524 and splayed legs 522 and 523 apply compressive forces to the wall 2 and the attachment device 20 to securely fastening the attachment device 20 to the vessel 1.

Figs. 34 and 35 depict a fastener 530 according to another embodiment of the present invention. Fastener 530 is a spring type fastener, which may comprise a coil spring. The fastener 530 is also formed from a wire-like material. The fastener 530 comprises a plurality of coils, as shown in Fig. 34. The end portions 531 and 532 of the wire-like material are preferably located on the same end of the fastener 530, as shown in Figs. 29, 30, and 34-36. Unlike fastener 510 and 520, the fastener 530 is temporarily elongated for storage in the fastener cartridge 535, as shown in Figs. 42, 43, and 46. As the fastener 530 is inserted through the attachment device 20 and wall 2 using the insertion means 450 on the penetration device 7, as shown in Fig. 44, the fastener 530 remains in an elongated position until the insertion means 450 is removed from the treatment specific hole 3 created in the wall 2 of the vessel 1 and the attachment device 20 formed by the penetration apparatus 7. The fastener 530 then assumes a collapsed position, as shown in Fig. 35. When the fastener 530 is in a fastened position within the vessel 1, the end portions 531 and 532 are positioned on one side of the attachment device 20 and wall 2 adjacent the attachment device 20, as shown in Fig. 45. The remaining portion of the fastener 530 is positioned on another side of the attachment device 20 and wall 2 adjacent the wall 2. The fastener 530 apply compressive forces to the wall 2 and the attachment device 20 to securely fastening the attachment device 20 to the

vessel 1. Fastener 530 may be formed from stainless steel; a superelastic alloy, for example titanium; or any other procedure/performance-appropriate materials.

Figs. 36, 37, 38, and 39 depict a fastener 540 according to another embodiment of the present invention. Fastener 540 is a coil spring type fastener. Fastener 540 comprises a mid-section 541, and semi-knotted end portions 542 and 543. The fastener 540 is also formed from a coil spring using materials, as described above. Preferably the fastener 540 is formed from stainless steel or a superelastic alloy, for example titanium. The fastener 540 is substantially linear, as shown in Fig. 36, when stored in a fastener cartridge, not shown. As the fastener 540 is inserted through the attachment device 20 and wall 2, the fastener 540 returns to its normally coiled configuration, as shown in Fig. 37. The fastener 540 applies compressive forces to the wall 2 and the attachment device 20 to securely fastening the attachment device 20 to the vessel 1 such that one semi-knotted overlapping end portion 542 is positioned adjacent the attachment device 20 and the other semi-knotted end portion 543 is positioned adjacent the wall 2 of the vessel 1, as shown in Figs. 38 and 39. Fig. 28 depicts an axially wound fastener 540. Fig. 40 depicts the fastener 540 of Fig. 38 secured to the wall 2. Fig. 39 depicts a radially wound fastener 540. Fig. 41 depicts the fastener 540 of Fig. 39 secured to the wall 2. The fastener 540 is termed a coiled coil spring type fastener. The coil spring which makes up the fastener is itself coiled during manufacture to assume the coiled configuration shown in Figs. 38-40. Fastener 540 is inserted through the attachment device 20 and the wall 2 using an insertion means in manner described above for fastener 530.

Figs. 49, 50, and 51 depict a fastener 550 according to another embodiment of the present invention. Fastener 550 is a coil spring type fastener formed from stainless steel, or a superelastic alloy, for example titanium, or any other procedure/performance appropriate materials. Fastener 550 is substantially linear, as shown in Fig. 36, when temporarily stored in a fastener cartridge, not shown.

The fastener 550 is a coiled coil spring type fastener which is coiled into its fastening shape during manufacture. Fastener 550 may comprise a plurality of coiled coil springs connected together. The embodiment shown in Fig. 49 comprises two entwined springs. The coil diameter and wire gauge for the depicted design are approximately .04 inches and .005 inches respectively. It, however, is contemplated that the present invention is not limited to

these dimensions. Outside coil diameters greater than 0.04 inches and less than 0.04 inches (such as, for example, 0.03 inches) are considered to be well within the scope of the present invention. The fastening force of the fastener 550 can be adjusted to suit a particular purpose by varying the coil diameter, wire gauge, number of coils, and number of coil springs. The fastener 550 is termed a coiled coil spring due to the fact that the coil spring is further coiled into a shape suitable for fastening during manufacture. The coiled coil springs that comprise the fastener 550 are spot welded together at at least one point along their lengths. Any suitable connection means that serves to keep the springs of the coiled coil in a fixed relationship with one another is within the scope of the present invention, and may be used in lieu of spot welding.

Fastener 550 comprises a midsection 551, and underlapping end portions 552 and 553. Prior to insertion the fastener 550 is temporarily straightened and placed about an insertion means. The fastener 550 is inserted through the attachment device 20 and the wall 2 using a process similar to that described above for fastener 530. Following insertion the core is removed and the fastener 550 returns to its normally coiled configuration, as shown in Figs. 49-51. The manufactured configuration of the fastener 550 provides the innovative method for securing the attachment device. The end portions 552 and 553 underlap at point 554 providing a locking mechanism for the fastener 550. The underlapping design of the fastener 550 prevents the attachment device 20 and the wall 2 from being pulled apart.

Figs. 52 and 53 depict a fastener 560 according to another embodiment of the present invention. Fastener 560 is a coiled coil spring type fastener formed from stainless steel, or a superelastic alloy, for example titanium, or any other procedure/performance appropriate materials. Similar to fastener 550, fastener 560 also utilizes coiled coil springs. Fastener 560 comprises a plurality of springs entwined together. The fastener 560 may be a single coiled coil spring or a plurality of coiled coil springs entwined together such as in fastener 550 described above. The preferred embodiment, as shown in Figs. 52 and 53, comprises two coiled coil springs 562 and 563. However, it is within the scope of the present invention that the fastener 560 may comprise more or less than two springs. The coil diameter and the wire gauge for the depicted design is approximately .04 inches and .005 inches respectively. The

fastening force of the fastener 560 can be adjusted to suit a particular purpose by varying the coil diameter, wire gauge, number of coils, and the number of springs.

Fastener 560 comprises a midsection 561, and end portions 562, 563, 564 and 565. Prior to insertion the fastener 560 is temporarily straightened and placed about an insertion means. The fastener 560 is inserted through the attachment device 20 and the wall 2. Following insertion, the insertion means is removed and fastener 560 unravels allowing the coiled coil springs 562 and 563 to return to their manufactured configuration, as shown in Figs. 52 and 53. The springs 562 and 563 may be spot welded together at at least one point along the midlength 561. The ends 564, 565, 566 and 567 of the springs are not welded together allowing them to separate when the insertion means is removed. Any suitable connection means that serves to keep the springs of the fastener 560 in a fixed relationship with one another is within the scope of the present invention, and may be used in lieu of spot welding.

Both fasteners 550 and 560, described above, use coiled coil springs with elastic/mechanical memories. Following insertion through the attachment device 20 and the wall 2, the coiled coil springs remember their manufactured form, and return to that form securing the attachment device 20 to the wall 2.

The holding potential of the coiled-coil fastener 570 may be further enhanced according to the embodiment of Figs. 56-58. The fastener 570 includes a central coiled fastener 571. The fastener 570 further includes at least one short coiled insert 572. The coiled insert 572 is located adjacent the end portion of fastener 571, as shown in Figs. 56 and 57. The short coiled insert 572 may be entwined with the fastener 571 at its ends to create unique head features. When the core over which the fastener 570 is temporarily positioned is removed the fastener 570 returns to its as-manufactured configuration. In this position, the at least one coiled insert 572 separates from the fastener 571 host creating a dimensional disturbance and additional resistance to fastener withdrawal. The at least one short coiled insert 572 is spot welded as shown at 573 to prevent complete separation from the fastener 571.

It is contemplated that the above-described coil spring fasteners may be formed either axially or radially wound coil springs. Furthermore, it is contemplated that coil spring may

have a circular, rectangular, triangular or other cross sectional configuration. It is also contemplated that the above-described fasteners may be surface treated to increase friction between the fastener and the surrounding tissue. Furthermore, it is contemplated that a polymeric material may be used rather than metal. In addition to varying coil diameter, wire gauge, number of coils and number of interwound springs to modify the holding force of the coiled-coil fastener, changing the spring's pitch between coils will also enhance the fastener's performance.

The fasteners according to the present invention are advanced to the surgical site either over or within the penetration assembly 7, as discussed above by activation of an advancing mechanism positioned remotely with respect to the patient. To minimize the complexity of the mechanism it is necessary to tightly control the over-mandrel length of the fastener. Compression of the fastener is inherent to its design as it transitions from its "as-manufactured" form to its "insertion-ready" form and will create significant functional problems unless anticipated in the fastener/fastener advance mechanism design. The inventors of the fasteners of the present invention have been able to remove fastener compression from the fastener advancement equation. According to one embodiment, the fastener can be dimensioned in such a way that the "slack" which is created within the fastener as it transitions from its "as-manufactured" to its "insertion-ready form," is taken up as it is wound over the insertion assembly 450. The inside diameter of the coil spring is the same as or slightly smaller than the insertion assembly 450 over which or within which it is temporarily positioned. This "dimensioning" facilitates both the pre-compression of the fastener on or within the penetration assembly 7 and its uniform advancement to the surgical site.

According to another embodiment, the fastener may be insert molded within a gelatin or similar dissolvable medium while in its "insertion-ready" form. The resultant "tube-like" component is non-compressible and facilitates both the fastener's easy loading over or within the penetration means and thereafter its uniform advancement to the surgical site where ultimately it spans the graft/adventitia matrix. The blood present dissolves the gelatin coating about and within the interstices of the fastener enabling resumption of its "as-manufactured" form and the compressive attachment of graft to vessel wall.

According to another embodiment, the fasteners may incorporate a dissolvable suture material. As shown in Fig. 59, the fastener **580** incorporates a dissolvable suture **581** wound between the individual coils **582** of the fastener **580**. The provision of the dissolvable suture **581** prevents longitudinal compression the fastener **580** on the insertion assembly, described above. Furthermore, the use of the suture permits uniform advancement of the fastener **580** along the insertion assembly and penetration assembly during the surgical procedure. It is contemplated that the use of the dissolvable suture **581** is not limited to fastener **580**. Rather, the use of the dissolvable suture **581** with any fastener having at least a coiled spring portion, including but not limited to the above-described embodiments, is considered to be well within the scope of the present invention.

It, however, will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing from the scope or spirit of the invention. For example, the fastening means mentioned above, may be pop-rivet fasteners, screw-type fasteners, and rapid hardening plastic extrudates, which are all contemplated to be within the scope of the present invention. Thus, it is intended that the present invention cover the modifications and variations of the invention, provided they fall within the scope of the appended claims and their equivalents.

Introducer Sheath Devices

Reference will now be made to a preferred embodiment of an introducer sheath device according to the present invention for use in the repair of abdominal aneurysms, an example of which is illustrated in Figs. 47 and 48. The introducer sheath device creates a protective passageway through the vessel through which the graft and repair devices are inserted. The introducer sheath device protects the arteries from damage that may occur when the repair apparatus and other devices are passed through the tortuous artery passageways during a surgical procedure.

Existing methods for repairing aneurysms utilize introducer sheath devices only in the femoral and common iliac arteries. Typically, guide wires extend from a femoral arteriotomy to an occlusion balloon placed within the proximal neck of the aorta at a point cephalad with respect to the abdominal aorta. Typically, others have gained access to the abdominal aorta via a femoral or common iliac arteriotomy into which is inserted an

introducer sheath device of between 18-28 Fr. diameter. The size of these devices may cause damage to the vessels through which they pass.

By contrast, the inventors of the present invention contemplate the use of more than one unique introducer sheath device **900**, as shown in Fig. 47. The sheaths **900** are introduced over a femoral/axillary guide wire. One introducer sheath device **900** extends from either an axillary incision or a brachial incision to the proximal neck of the vessel **1**. Another introducer sheath device **900** extends from a femoral incision to the distal neck of the vessel or common iliac/distal aorta transition. The introducer sheath devices according to the present invention that extend through the axillary vessel and through the femoral artery have similar constructions. However, the introducer sheath device that extends through the axillary artery has a smaller size in the range between 9-12 Fr. and is able to navigate the arteriotomy/proximal aorta passageway without problem. The smaller size permits access to the aorta via either the left brachial or axillary artery, both of which are significantly smaller than the femoral or common iliac arteries. This procedure, previously, beyond consideration, may now significantly benefit these vascular procedures.

Each introducer sheath device **900** comprises a housing **910** having a hollow interior **911** that permits the passage of the tube graft and other repair apparatus through the introducer sheath device to the vessel **1**. The housing **910** preferably includes multiple lumen or passageways formed therein. The repair apparatus are introduced through a multiport introducer assembly an opening **912** in the end portion of the housing **910**. In a preferred embodiment, the housing **910** is a thin walled co-extrusion having an outer surface formed, for example, from silicon and an inner surface formed, for example, from Teflon®. Alternatively, the housing **910** may be formed of a suitable polymer having similar properties.

The introducer sheath device **900**, also, comprises positioning assembly **920** for maintaining the sheath **900** in proper orientation within the vessel. In a preferred embodiment, the positioning assembly **920** comprises an inflatable cuff **921** located at one end of housing **910**. The positioning assembly **920** further comprises an inflation device for inflating the cuff **921**. The inflation device in a preferred embodiment comprises a plurality of passageways **923** formed within the wall of housing **910**. A suitable fluid, such as saline,

is supplied from an external source through the passageways 923 to fill the cuff 921. The passageways 923 terminate at inflatable cuff 921, as shown in Fig. 47. The positioning assembly 920 includes a silicon balloon which is connected to the housing opposite the introducer assembly. The silicon balloon is preferred for several reasons. First, unlike other polymeric balloons, the silicon balloon is capable of material expansion of up to 800% and will upon deflation return to its original shape. Other materials require "pre-forming" before integration within a device; such a device is more bulky and less able to totally deflate once it has served its clinical purpose. Utilization of silicon facilitates a low profile balloon which can be made co-planar with the multi-lumen housing to which it is attached. Additionally, housing termination details and smooth transitions -- balloon to housing, may be affected.

The housing 910 includes a central channel. The housing is formed of a multi-layer assembly comprising a fluoronated polymer core over which a polyurethane layer is extruded. A multi-stranded wire braid is located on top of the polyurethane layer about which a multi-lumen polymeric profile is co-extruded. This housing configuration provides certain benefits. First, the internal surface of the housing also has a low coefficient of friction which aids in the intraluminal passage of both penetration and visualization devices. The braided layer provides kink resistance, torquability and flexibility to the housing. locating the braid within the multi-lumen co-extrusion allows non-destructive access to the peripheral lumen. Furthermore, the co-extruded assembly provides a thermoplastic exterior surface to which the positioning assembly may be readily attached.

Alternatively, the housing may include a multi-lumen polymeric profile about which a multi-stranded wire braid is attached. Thereafter the assembly receives a polymeric coating which binds the three tubular layers to one another.

Prior introducer sheath devices have not been able to control the loss of significant amounts of blood through the open end of the introducer sheath device that is positioned outside of the body. Others have attempted to prevent this blood loss through the use of complex clamping systems. The present invention provides a unique seal arrangement to prevent significant blood loss. The introducer sheath device 900 efficiently seals the smaller surgical devices of the present invention which are typically 3 mm in diameter. Presently available surgical devices used with similar procedures typically have diameters in the range

of 6-9 mm. The use of these larger diameter devices in combination with currently available introducer sheaths typically results in significant and problematic blood loss. The sheath 900 may be used with these larger diameter devices without significant blood loss due to its innovative sealing arrangement.

5 A seal 930 located at one end of the housing 910 adjacent opening 912 prevents significant blood loss. The seal 930 comprises an expanded housing assembly 931. A self-sealing gel-like material 932 is located within the expanded housing assembly 931. The material 932 permits the insertion of the repair apparatus through the material 932, which forms a seal around the repair apparatus. As the repair apparatus is removed from the
10 introducer sheath device 900 and the sealing material 932, the material 932 forms a seal behind the repair apparatus as it is removed through opening 912.

 A detailed view of the seal 930 is shown in Fig. 54. The seal assembly 930 may comprise the expanded housing assembly 931 and an end cap 935. The seal material 932 is preferably a polymeric gel, sphincter-like in shape, having a central opening for receiving a
15 surgical device 940. When the surgical device or repair apparatus 940 is removed from the sheath 900 the sphincter-like opening in material 932 closes, creating a tight seal and preventing the loss of blood. The seal material 932 rests on a ledge or seat 936 located in the housing assembly 931. The seal material 932 is held in place by a retaining ring 933, which is secured to the interior of the housing assembly 931.

20 The expanded housing assembly 931 is permanently attached to the housing 910, as shown in Fig. 55, at 915. An infusion port 925 is provided to allow for the supply or removal of the fluid or gas, which inflates or deflates the cuff 921. The fluid or gas travels from the infusion port 925 to the cuff 921 via the lumen 923 shown in Fig. 47.

 The seal 930 may be used with or without the end cap 935. The end cap 935 provides
25 additional protection against blood loss. The end cap 935 is inserted into the opening 912 in the expanded housing assembly 931 opposite the housing 910. The end cap includes a thumbwheel portion 938 to facilitate connection with the housing assembly 931. The end cap 935 has both internal and external sealing means. The internal sealing means is comprised of a V-type sealing ring 937 which provides a fluid-tight seal between the surgical device 940
30 and the end cap 935. The external sealing means is provided by an external groove 939 and

a sealing ring 934. Sealing ring 934 is preferably an O-ring formed from polymeric material. The end cap 935 may be modified as required to accommodate different surgical devices. The expanded housing assembly 931, however, is capable of accommodating a variety of devices without modification.

5 The multi-port introducer assembly includes lured entryways for balloon inflation (positioning assembly), pressure monitoring/fluid control. (IVA) and a seat-protected device entry. With the exception of seal and cap details, the multi-port introducer assembly is an insert molding about the housing. The seal includes a thermoplastic elastomer molding having a lubricious polymeric coating, which is able to form a blood-tight seal about inserted
10 instruments having very small diameters while at the same time enabling their easy rotation within the introducer assembly. The cap component snap-fits to the introducer molding and holds the seal component in position.

 The general arrangement of the sheath device 900 is shown in Fig. 55. The surgical device or repair apparatus 940 is inserted into the housing 910 through the seal 930 which
15 is located outside the skin 950. As described above, the positioning assembly 920 is located in the vicinity of the aneurysm so maintaining the sheaths 900 correct orientation within the vessel.

 It will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing
20 from the scope or spirit of the invention. It is intended that the present invention cover the modifications and variations of the invention, provided they fall within the scope of the appended claims and their equivalents.

Method of Repairing an Aneurysm

 Reference will now be made in detail to a preferred embodiment of the method of
25 repairing an aneurysm utilizing the above described components according to the present invention.

IntraVascular Endoscopy (IVE) Based Repair Method

 The IntraVascular Endoscopy (IVE) based repair method will be described in connection with the use of a proximal graft assembly 10 and distal graft assembly 20.
30 Introducer sheath devices 900 are placed by femoral arteriotomy in both common iliacs under

radiological guidance such that the positioning assembly 920 is positioned at the common iliac/aortic bifurcation transition. A guide wire is fed from one femoral incision to the other, also under guidance. A distal graft assembly 20 is fed over the guide wire until the attachment cuff 21 appears directly above the carina at the bifurcation, as shown in Fig. 1.

5 A second guide wire 160 is now fed under radiological guidance between one femoral incision and the left axillary incision. Another introducer sheath device 900 is fed from the axillary until the positioning assembly 920 reaches the infrarenal aorta at which time it is inflated. The repair apparatus 5 is then fed through the introducer sheath device 900 over guide wire 160 from either the femoral or axillary access to the midpoint of the aortic
10 aneurysm. The visualization apparatus 6 is then fed through the hollow interior 211 of housing 200 to the area of the wall 2 to which the attachment cuff 22 is to be attached. The guide wires 170 are then manipulated to adjust the orientation of the visualization apparatus 6 to permit viewing of the wall 2 as described above, such that an image appears on the monitor. An image of the wall 2 appears on the monitor. The visualization apparatus 6 is
15 then removed and the penetration apparatus 7 is then inserted through the hollow interior 211. The guide wires 170, as described above, permit the penetration apparatus to be positioned in the same position as the visualization apparatus 6. The tracking means 440 pinpoints the location of the penetration means 420 with respect to the wall 2 and attachment cuff 22 as viewed on the monitor. The primary and secondary penetration means 420 and 430 are then
20 operated to form treatment specific holes within the cuff 22 and wall 2, as described above. The primary penetration means 420 is then retracted and a fastener is then inserted within the treatment specific hole using the insertion means 450. The location of the penetration apparatus 7 is then adjusted to repeat the process over the area previously viewed by the visualization apparatus 6. The penetration apparatus 7 is then removed and the visualization
25 apparatus 6 is reinserted. The viewing and fastening process is alternately repeated until the attachment cuff 22 is firmly attached to the wall 2.

The repair apparatus 5 is removed once the attachment cuff 22 is secured to the wall
2. The proximal graft assembly 10 is then inserted in an inverted manner through the femoral arteriotomy over the guide wire 160 to the position shown in Fig. 1. The repair apparatus 5
30 is then fed through the introducer sheath device 900 over the guide wire 160 from either a

femoral or axillary access to a position adjacent the attachment cuff 12. The visualization apparatus 6 and the penetration apparatus 7 are then alternately inserted in the manner described above to secure the attachment cuff 12 to the wall 2. In the event that a standard graft 3 is used, the inverted graft 3 is secured directly to the wall 2 in a similar manner.

Alternatively, a self-expanding stent 30 may be used in combination with fasteners to secure the graft 3 to the wall 2. The repair apparatus 5 is then removed.

Once the proximal graft assembly 10 or 3 are secured in place, the first guide wire is removed and the graft 3 or 10 is invaginated. The tubular legs 11 are then inserted into the attachment tubes 22. Self-expanding stents 30 are then used to secure the attachment tubes 22 and tubular legs 11 firmly together. The guide wire 160 is then removed. The positioning assemblies 920 are deflated and the introducer sheath device 900 are removed from the femoral and axillary arteries. The incisions are then closed completing the repair process. The outlined procedure according to the present invention is far less intrusive than current known techniques. As a result, a patient's recovery period should decrease.

IntraVascular Ultrasound Repair Method

The intravascular ultrasound repair method will be described in connection with the use of a proximal graft assembly 10 and distal graft assembly 20. Introducer sheath device 900 are placed by femoral arteriotomy in both common iliacs under radiological guidance such that the positioning assembly 920, as described above in connection with the IntraVascular Endoscopy (IVE) based repair method. A distal graft assembly 20 is fed over a guide wire, as described above, until the attachment cuff 21 appears directly above the carina at the bifurcation, as shown in Fig. 1.

A second guide wire 160 is now fed under guidance between one femoral incision and the left axillary incision. Another introducer sheath device 900 is fed from the axillary until the positioning assembly 920 reaches the infrarenal aorta at which time it is inflated. The repair apparatus 50 is then fed through the introducer sheath device 900 over guide wire 160 to the midpoint of the aortic aneurysm. The visualization apparatus 600 is then positioned adjacent the area of the wall 2 to which the attachment cuff 22 is to be attached. The scanning catheter is drawn caudad providing images of the distal aortal common iliac transition on an external monitor. The repair apparatus 50 is then oriented such that the

penetration apparatus **700** is adjacent the area where the attachment cuff **21** is to be attached to the wall **2**.

The primary and secondary penetration means **420** and **430** are then operated to form treatment specific holes within the cuff **22** and wall **2**, as described above. The primary penetration means **420** is then retracted and a fastener is then inserted within the treatment specific hole using the insertion means **450**. The location of the penetration apparatus **700** is then adjusted to repeat the process over the area previously viewed by the visualization apparatus **600**. The repair apparatus **50** is then oriented such that the visualization apparatus **600** may scan another portion of the wall **2**. The viewing and mounting process is alternately repeated until the attachment cuff **22** is firmly attached to the wall **2**.

The repair apparatus **50** is removed once the attachment cuff **22** is secured to the wall **2**. The proximal tube graft assembly **10** is then inserted in an inverted manner over the guide wire **160** to the position shown in Fig. 1. The repair apparatus **50** is then inserted through a femoral incision over the guide wire **160** to a position adjacent the attachment cuff **12**. The visualization apparatus **600** and the penetration apparatus **700** are then alternately operated in the manner described above to secure the attachment cuff **12** to the wall **2**.

Once the proximal graft assembly **10** is secured in place, the first guide wire and the repair apparatus **50** are removed and the proximal graft assembly **10** is invaginated. The tubular legs **11** are then inserted into the attachment tubes **22** or vice verse. Self-expanding stents **30** are then used to secure the attachment tube **22** and tubular legs **11** firmly together. The guide wire **160** is then removed. The positioning assemblies **920** are deflated and the introducer sheath devices **900** are removed from the femoral and axillary arteries. The incisions are then closed completing the repair process.

While this invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, the preferred embodiments of the invention as set forth herein are intended to be illustrative, not limiting. Various changes may be made without departing from the spirit and scope of the invention as defined in the following claims.

WE CLAIM:

1. A fastener for use during a surgical procedure for securing a surgical component to a vessel wall, said fastener comprising:

flexible fastening means for securing the surgical component to the vessel wall under a compressive force;

5 wherein said fastening means has a first portion located on one side of the surgical component and the vessel wall, a second portion located on another side of the surgical component and the vessel wall, and an intermediate portion connecting said first portion and said second portion, said intermediate portion extending through the vessel wall and the surgical component, whereby said first portion, second portion and said intermediate portion
10 act together to apply a compressive force to the surgical component and the vessel wall to secure the surgical component to the vessel wall; and

wherein said fastening means further includes at least one supplemental fastening means for securing the surgical component to the vessel wall, said at least one supplemental fastening means being located on at least one of said first portion and said second portion.

2. The fastener according to claim 1, wherein said fastening means includes at least one spring assembly, and said supplemental fastening means includes at least one supplemental spring assembly.

3. The fastener according to claim 2, wherein each of said first portion, said second portion and said at least one supplemental spring assembly extends substantially parallel to the vessel wall.

4. The fastener according to claim 2, wherein said fastening means comprises a plurality of entwined coil springs.

5. The fastener according to claim 2, wherein said supplemental spring assembly includes a coil spring.

6. The fastener according to claim 2, wherein said supplemental fastening means includes a first supplemental spring assembly connected to said first portion of said fastening means.

7. The fastener according to claim 6, wherein said supplemental fastening means includes a second supplemental spring assembly connected to said second portion of said fastening means.

8. The fastener according to claim 2, further comprising:

means for connecting at least a portion of said at least one supplemental spring assembly to said spring assembly.

9. The fastener according to claim 2, wherein said fastener has a first orientation for inserting said fastener through the vessel wall and the surgical component, and a second orientation when said fastener is in a secured position.

10. The fastener according to claim 9, wherein said spring assembly and said at least one supplemental spring assembly are aligned along a longitudinal axis when said fastener is in said first orientation.

11. The fastener according to claim 10, wherein said spring assembly and said at least one supplemental spring assembly are displaced with respect to each other and from said longitudinal axis when said fastener is in said second orientation.

12. The fastener according to claim 9, wherein said fastener is in tension when in said first orientation and a relaxed state when in said second orientation, said fastener further comprising:

control means for controlling the compression of said fastener in said first orientation.

13. The fastener according to claim 12, wherein said spring assembly and said at least one supplemental spring assembly are coil springs, wherein each of said coil springs has a plurality of individual coils.

14. The fastener according to claim 13, wherein said control means is located between a plurality of said individual coils.

15. The fastener according to claim 14, wherein said control means includes a suture material disposed between said plurality of said individual coils.

16. The fastener according to claim 15, wherein said suture material is formed from a dissolvable material, such that said suture material dissolves after said fastener has been secured in said second orientation.

17. The fastener according to claim 12, wherein said control means includes a dissolvable material formed on said fastener means and said supplemental fastener means.

18. A fastener for use during a surgical procedure for securing a surgical component to a vessel wall, said fastener comprising:

flexible fastening means for securing the surgical component to the vessel wall under a compressive force;

5 wherein said fastening means has a first portion located on one side of the surgical component and the vessel wall, a second portion located on another side of the surgical component and the vessel wall, and an intermediate portion connecting to said first portion and said second portion, said intermediate portion extending through the vessel wall and the surgical component, whereby said first portion, second portion and said intermediate portion
10 act together to apply a compressive force to the surgical component and the vessel wall to secure the surgical component to the vessel wall;

wherein said fastening means has a first orientation for inserting said fastening means through the vessel wall and the surgical component, and a second orientation when said fastening means applies the compressive force to the surgical component and the vessel, said
15 fastening means being in tension when in said first orientation; and

control means for controlling the compression of said fastening means in said first orientation.

19. The fastener according to claim 18, wherein said control means includes a dissolvable material formed on said fastening means.

20. The fastener according to claim 19, wherein said fastener further includes at least one supplemental fastening means for securing the surgical component to the vessel wall, said at least one supplemental fastening means being located on at least one of said first portion and said second portion.

21. The fastener according to claim 18, wherein said fastening means includes at least one coil spring assembly.

22. The fastener according to claim 21, wherein said at least spring assembly has a plurality of individual coils, wherein said control means is located between a plurality of said individual coils.

23. The fastener according to claim 22, wherein said control means includes a suture material disposed between said plurality of said individual coils.

24. The fastener according to claim 23, wherein said suture material is formed from a dissolvable material, such that said suture material dissolves after said fastener has been secured in said second orientation.

25. The fastener according to claim 23, wherein said fastener further includes at least one supplemental fastening means for securing the surgical component to the vessel wall, said at least one supplemental fastening means being located on at least one of said first portion and said second portion.

26. The fastener according to claim 25, wherein said supplemental fastening means includes at least one coil spring assembly having a plurality of individual coils.

27. The fastener according to claim 26, wherein said suture material is disposed between a plurality of said coils of said supplemental fastening means.

28. A fastener for use during a surgical procedure for securing a surgical component to a vessel wall, said fastener comprising:

flexible fastening means for securing the surgical component to the vessel wall under a compressive force;

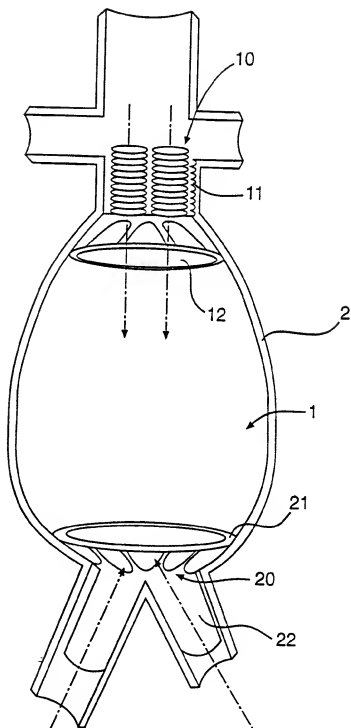
5 wherein said fastening means has a first portion located on one side of the surgical component and the vessel wall, a second portion located on another side of the surgical component and the vessel wall, and an intermediate portion connecting to said first portion and said second portion, said intermediate portion extending through the vessel wall and the surgical component, whereby said first portion, second portion and said intermediate portion
10 act to apply a compressive force to the surgical component and the vessel wall to secure the surgical component to the vessel wall;

at least one supplemental fastening means for securing the surgical component to the vessel wall, said at least one supplemental fastening means being located on at least one of said first portion and said second portion;

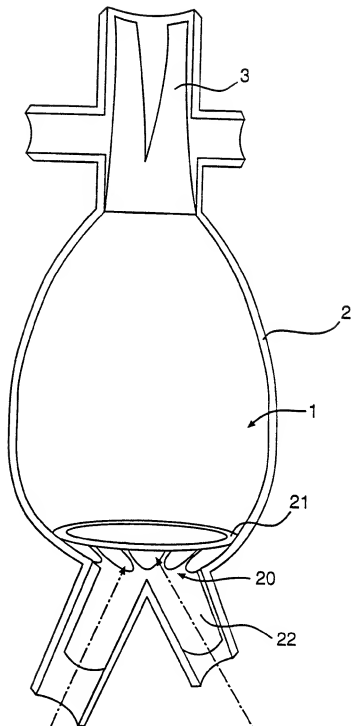
15 wherein said fastening means and supplemental fastening means have a first orientation for inserting said fastener through the vessel wall and the surgical component, and

a second orientation when said fastener applies the compressive force to the surgical component and the vessel, said fastener being in tension when in said first orientation; and
control means for controlling the compression of said fastener in said first orientation.

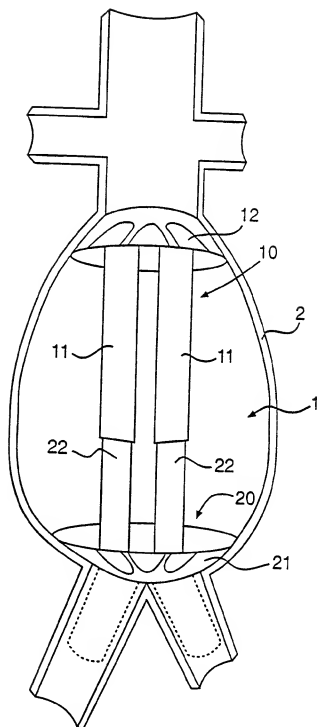
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**FIG. 1**

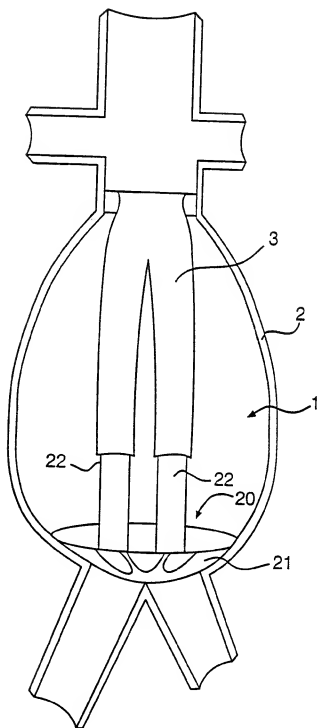
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**FIG. 2**

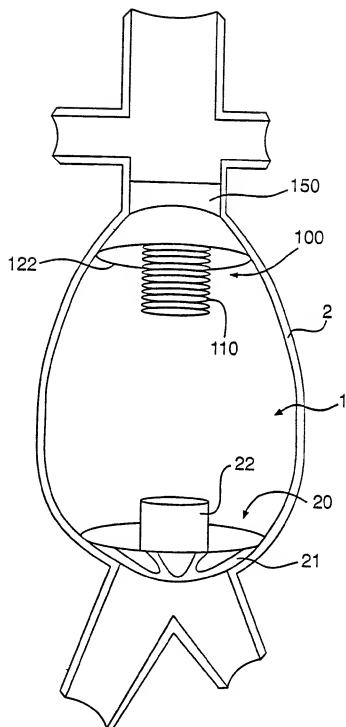
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**FIG. 3**

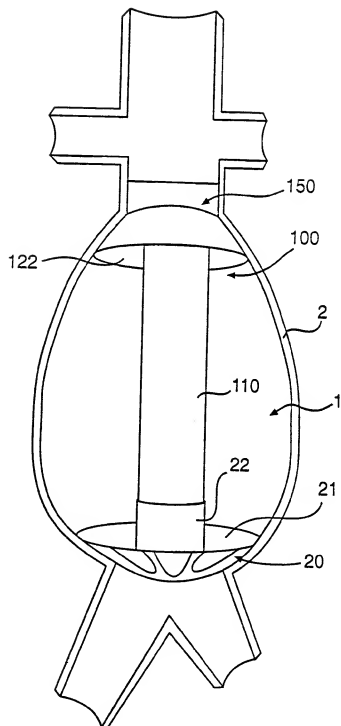
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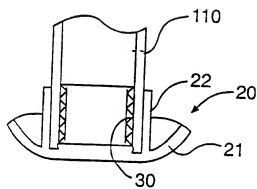
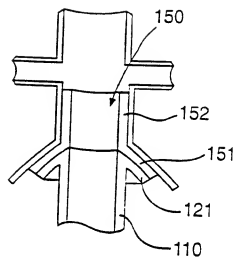
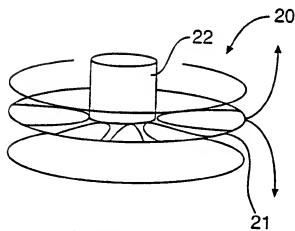
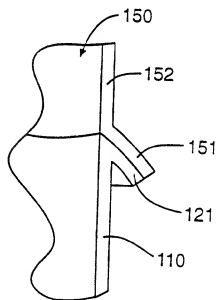
**FIG. 4**

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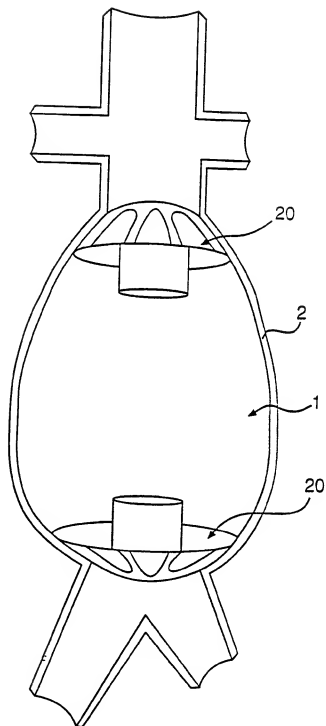
**FIG. 5**

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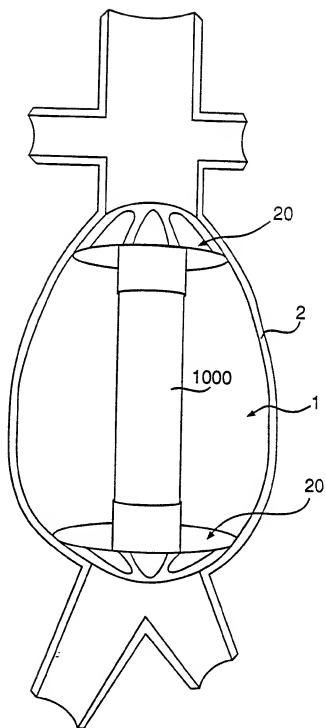
**FIG. 6**

**FIG. 7****FIG. 8****FIG. 11****FIG. 9**

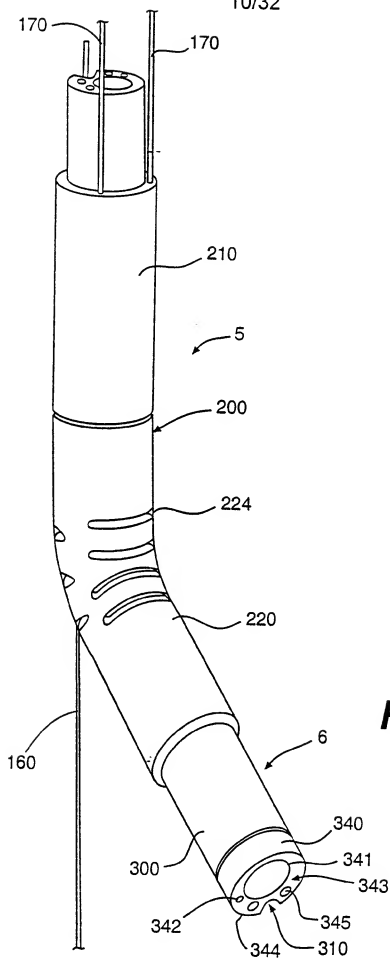
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**FIG. 10**

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**FIG. 12**

10/32

**FIG. 13**

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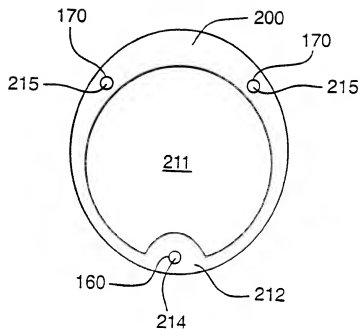


FIG. 14

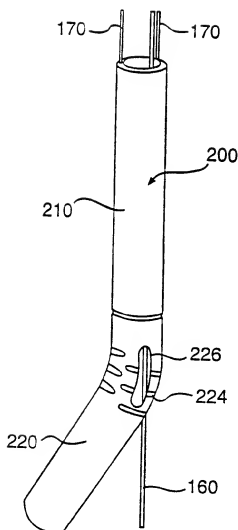


FIG. 16

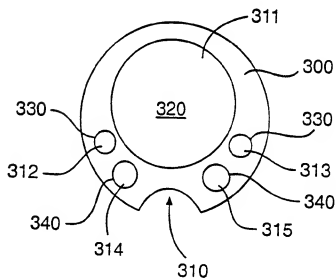
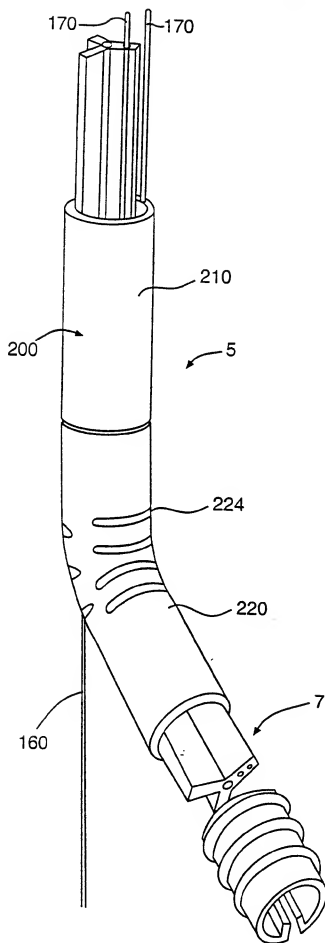
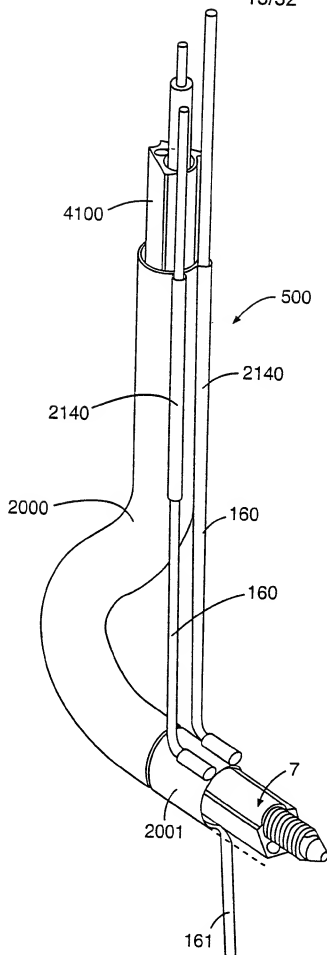


FIG. 15

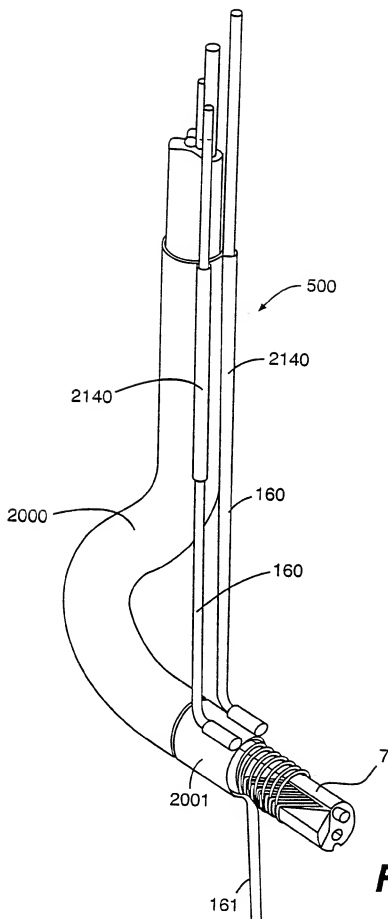
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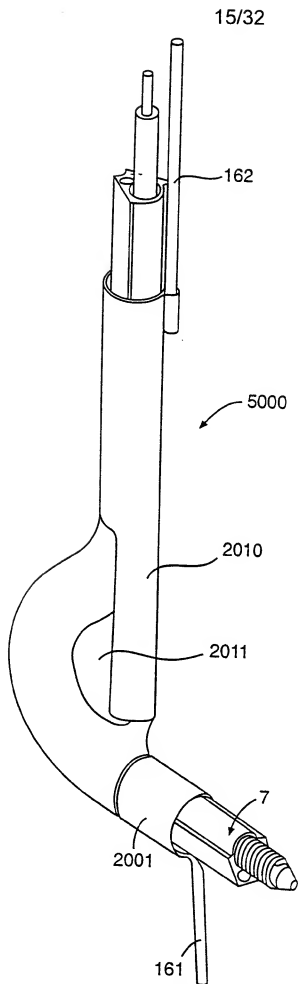
**FIG. 17**

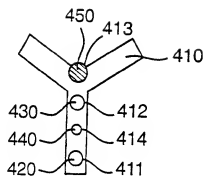
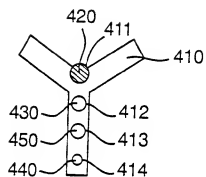
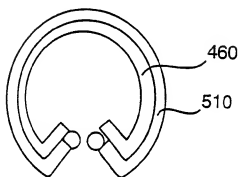
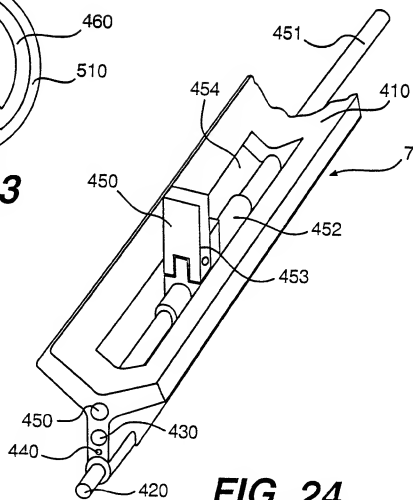
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**FIG. 18**

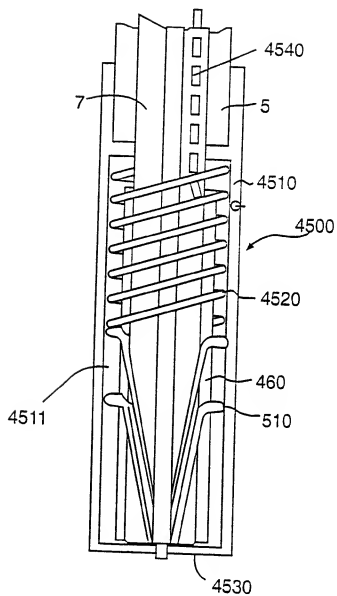
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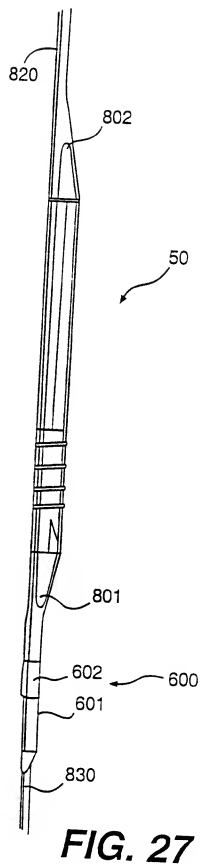
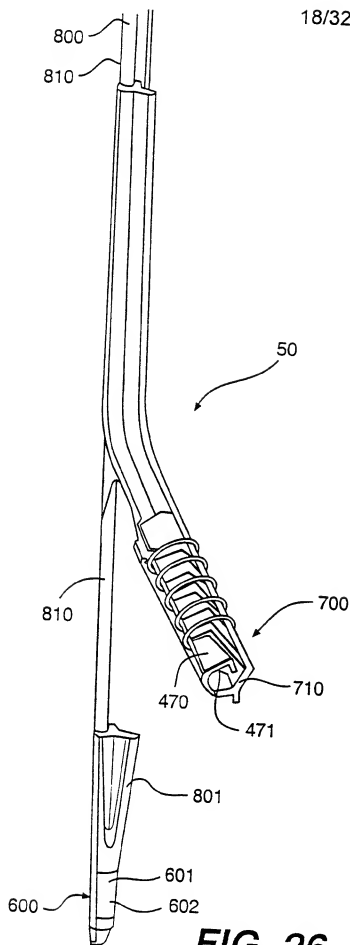
**FIG. 19**

**FIG. 20**

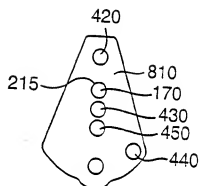
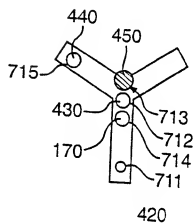
**FIG. 21****FIG. 22****FIG. 23****FIG. 24**

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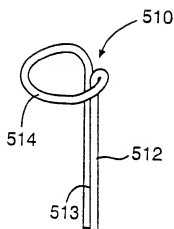
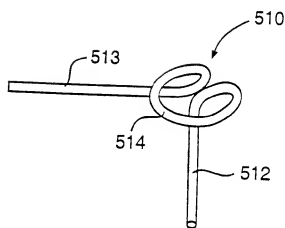
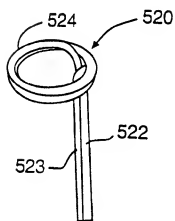
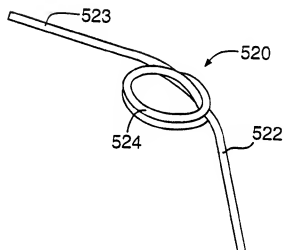
**FIG. 25**

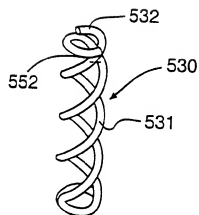
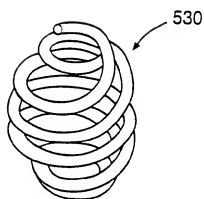
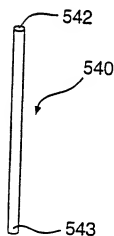
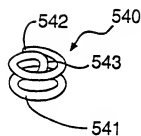


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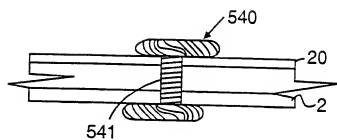
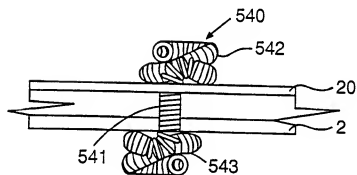
**FIG. 28****FIG. 29**

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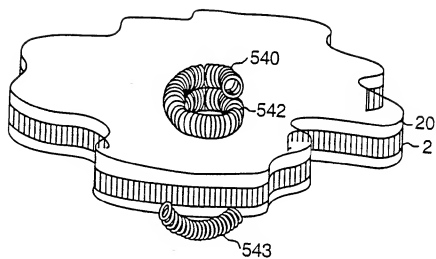
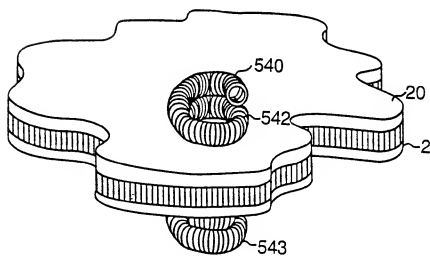
**FIG. 30****FIG. 31****FIG. 32****FIG. 33**

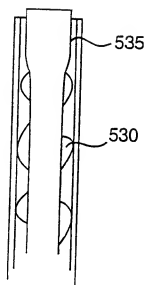
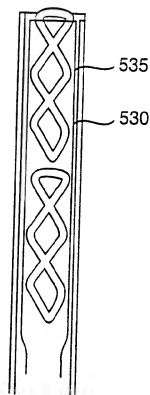
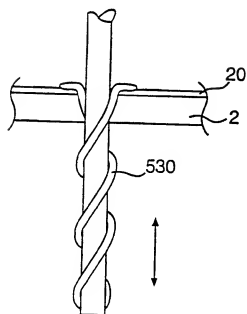
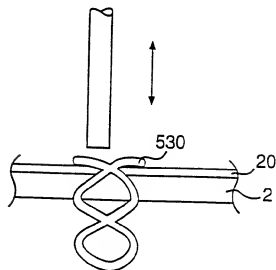
**FIG. 34****FIG. 35****FIG. 36****FIG. 37**

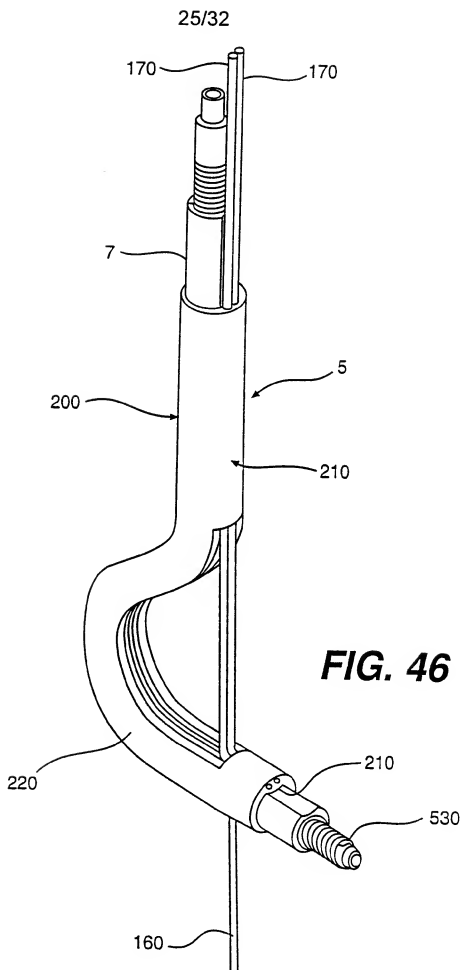
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**FIG. 38****FIG. 39**

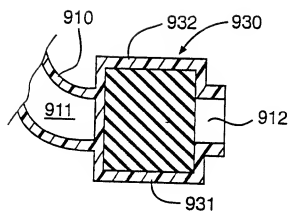
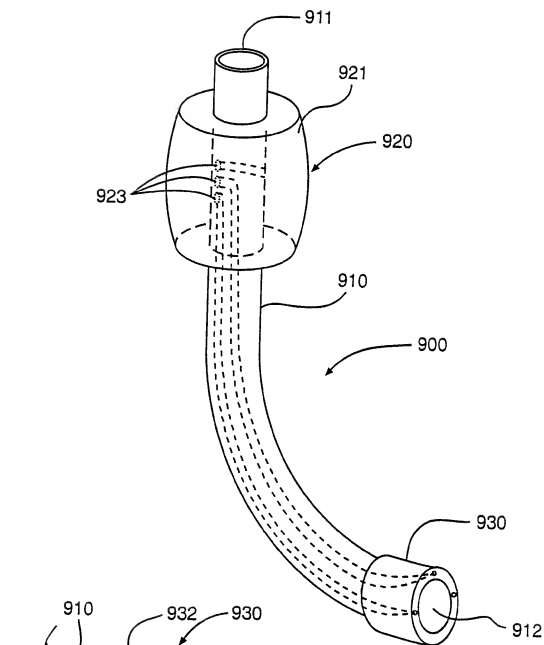
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**FIG. 40****FIG. 41**

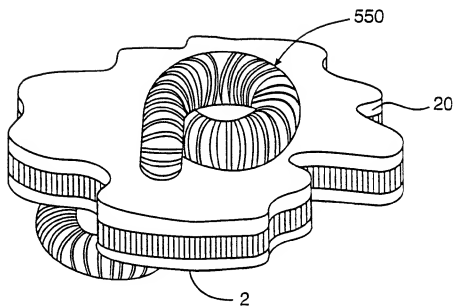
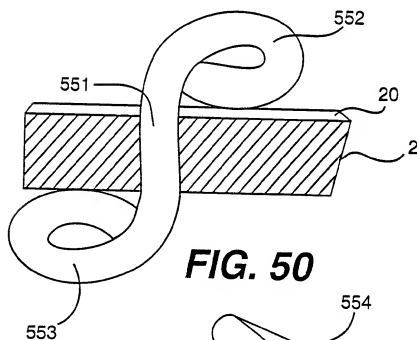
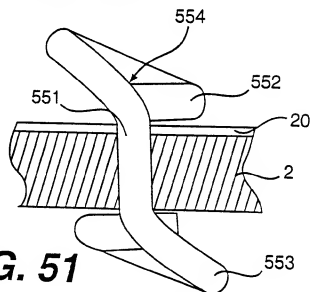
**FIG. 42****FIG. 43****FIG. 44****FIG. 45**



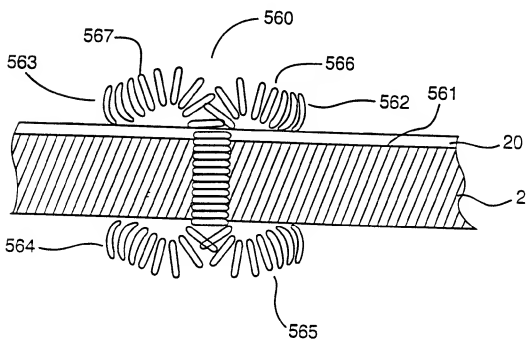
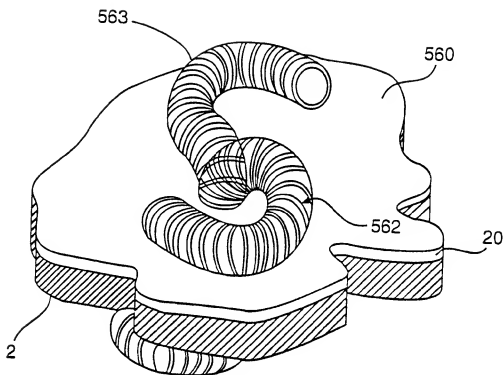
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**FIG. 47****FIG. 48**

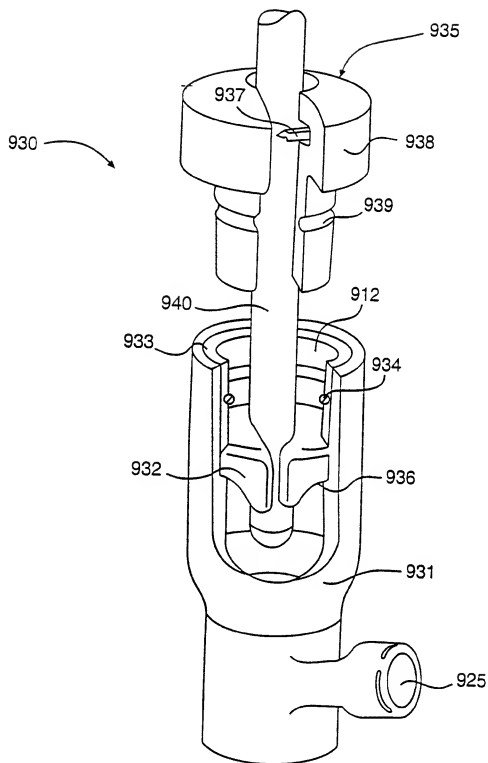
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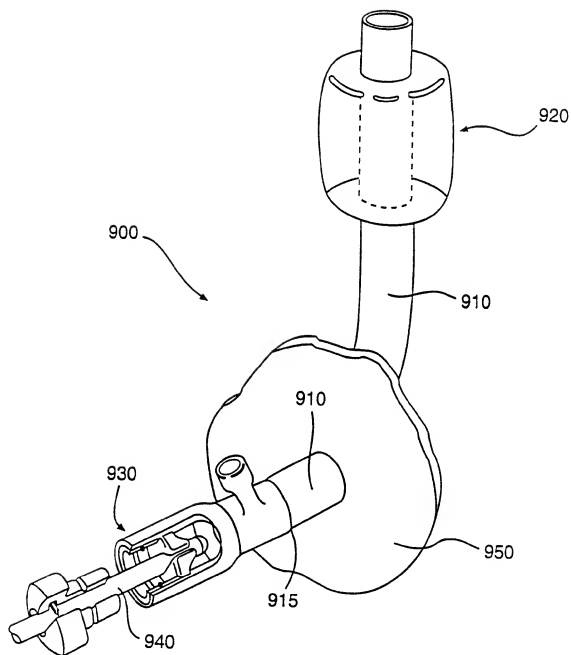
**FIG. 49****FIG. 50****FIG. 51**

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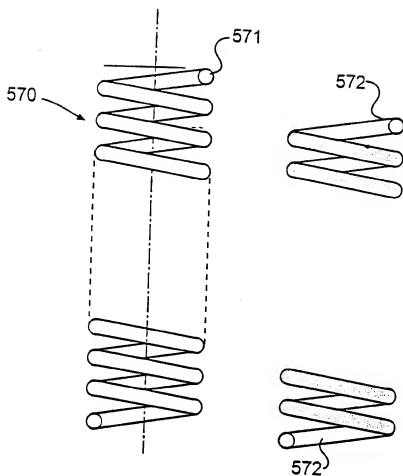
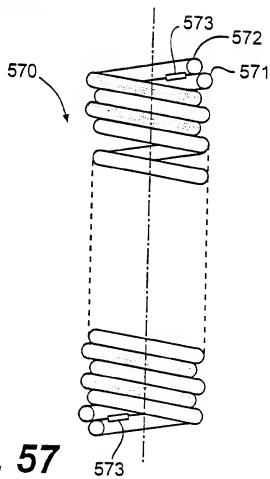


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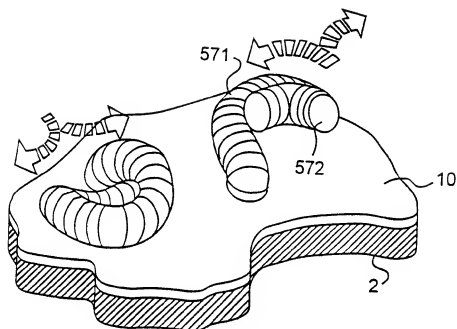
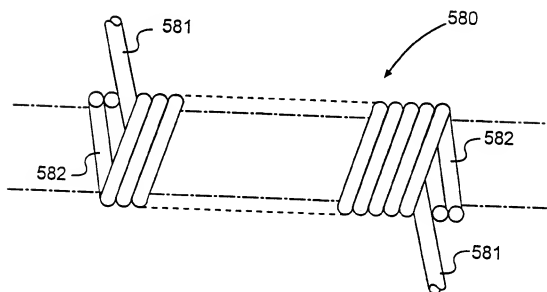
**FIG. 54**

**FIG. 55**

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**FIG. 56****FIG. 57**

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**FIG. 58****FIG. 59**

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/29348

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61B 17/00
US CL : 606/153

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/151, 153, 155, 157, 158

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,366,462 A (KASTER et al.) 22 November 1994, entire document.	1-28

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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Date of mailing of the international search report

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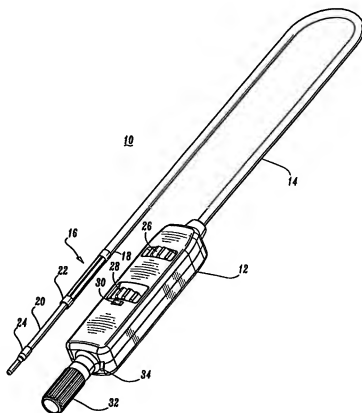
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(21) International Application Number: PCT/US00/10921		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).	
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(71) Applicant (for all designated States except US): UNITED STATES SURGICAL CORPORATION [US/US]; 150 Glover Avenue, Norwalk, CT 06856 (US).			
(71)(72) Applicants and Inventors: ARANYI, Ernest [US/US]; 170 Stepney Road, Easton, CT 06612 (US). RATCLIFF, Keith [US/US]; 14 Concord Ridge, Newton, CT 06470 (US). MCGARRY, Richard [US/US]; 11 East Meadow Lane, Norwalk, CT 06851 (US). RENDE, Frank [US/US]; 58 George Street, Stamford, CT 06902 (US).		Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	
(74) Agents: GERSHON, Neil, D. et al.; United States Surgical Corporation, 150 Glover Avenue, Norwalk, CT 06856 (US).			

(54) Title: SECOND GENERATION COIL FASTENER APPLIER WITH MEMORY RING

(57) Abstract

There is provided an endo-vascular fastener applier for fastening a vascular graft to a vessel with at least one fastener. The applicator generally includes a tubular body (14) configured for positioning within the vessel, and an expandable portion (16) adjacent the tubular body (19). A fastener applying head (16) is movably mounted within the expandable portion. The applicator further includes a handle assembly (12) mounted on a proximal end of the tubular body (14). The handle assembly (12) generally includes control (28) for expanding the expandable portion (16), pivoting, rotating the fastener applying head (42) and for driving a fastener out of a fastener driving head (42). Preferably, the applicator also includes a storage chamber extending from a distal end of the expandable portion (16), and containing a plurality of fasteners.



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**SECOND GENERATION COIL FASTENER
APPLIER WITH MEMORY RING**

CROSS REFERENCE TO RELATED APPLICATIONS

This patent application claims the benefit of U.S. Provisional Application Serial No. 60/130,922, filed April 23, 1999, the entire contents of which are incorporated by reference herein.

BACKGROUND

1. Technical Field

This disclosure relates generally to vascular grafts for intraluminal delivery and, in particular, to a method and apparatus for repairing diseased or damaged sections of a vessel by fastening a prosthesis within the vessel.

2. Description of Related Art

Diseased or damaged blood vessels often cause weakening of the vessel wall resulting in an aneurysm whereby a blood vessel and especially an artery have a section of abnormal blood-filled dilation. For example, an abdominal aortic aneurysm is a sac caused by an abnormal dilation of the wall of the aorta, a major artery of the body as it passes through the abdomen.

The abdominal aortic aneurysm usually arises in the infrarenal portion of the arteriosclerotically diseased aorta, for example, below the kidneys. Left untreated, the aneurysm will eventually cause rupture of the sac with ensuing fatal hemorrhaging

in a very short time. High mortality associated with rupturing led the state of the art into trans-abdominal surgical repair of abdominal aortic aneurysms.

Surgery involving the abdominal wall, however, is a major undertaking with associated risks. This type of surgery, in essence, involves replacing the diseased
5 and aneurysmal segment of blood vessel with a prosthetic device which typically is a synthetic tube, or graft, usually fabricated of either DACRON™, TEFLON™, or other suitable material.

The present state of the art for intraluminal repair of a vessel does not fasten a prosthesis to the remaining aortic wall. For example, U.S. Patent Nos.
10 5,571,171 and 5,571,173 disclose a method and apparatus for treating an abdominal aortic aneurysm by supplying a prosthesis or an aortic graft for intraluminal delivery that does not fasten the graft to the remaining aortic wall.

Presenting an aortic graft through the aorta by intraluminal delivery avoids major invasive surgery. The '171 and '173 patents disclose an aortic graft that
15 is delivered intraluminally to the aneurysm site. The aortic graft is secured to the remaining aortic wall by a balloon that is inflated thereby causing the graft to contact and adhere to the remaining aortic wall.

The major disadvantages related to the combination of endovascular expanders, such as a balloon or stent, and prosthesis is the dilation of the natural artery
20 with consequent migrations and periprosthetic losses. Upon withdrawal of the expander, the tissue is caused to collapse and the prosthesis disengages from the remaining aortic wall and tends to migrate to a location away from the aneurysm site to

be repaired. The migration and movement of the disengaged aortic graft would then obstruct the affected vessel. The migration and movement of the aortic graft requires further treatment on the patient to remove the failed attempt to attach the aortic graft to the remaining aortic wall.

5 Further treatment may include major surgery that is hazardous and traumatic to the patient. Major surgery to remove the aortic graft defeats the benefits of intraluminal delivery of the aortic graft. The current state of the art does not disclose a fastener applicator that intraluminally delivers a vascular graft and endoluminally applies internal fasteners to fasten a prosthesis in place.

10 Accordingly, there is a present need for a fastener applicator that intraluminally delivers a vascular graft to a site within a vessel and applies fasteners to pass through both a prosthesis and the thickness of a vessel wall. The fastened prosthesis should also have the capability of following dilation of a vessel.

An exemplary instrument also suitable for use in installing a novel graft
15 assembly is disclosed in provisional patent application No. 60/101,050 entitled, "Endovascular Fastener Applicator", filed with the U.S. Patent and Trademark Office on September 18, 1998 and in International Application No. PCT/US99/21414, filed September 17, 1999, the entire disclosures of which are incorporated by reference herein.

20 **SUMMARY**

There is provided an endovascular fastener applicator for endoluminally fastening a prosthetic graft to a vessel with at least one fastener. The applicator

generally includes a tubular body configured for positioning within a vessel and an expandable portion disposed adjacent a distal end of the tubular body and being expandable to support a prosthetic in contact with an inner surface of a vessel. A fastener applying head is rotatably mounted on the distal end of the tubular body and is

5 movable between a load position longitudinally aligned with the tubular and a firing position oriented approximately 90° with respect to the tubular body. The applicator also includes a handle assembly mounted on a proximal end of the tubular body and having a first control to expand the expandable portion, a second control to pivot the fastener driving head to the firing position and rotate the fastener driving head about the

10 longitudinal axis of the tubular body.

The handle assembly further includes a third control to move a fastener out of the fastener driving head and into tissue and move a fastener carrying slider into engagement with the tissue.

Preferably, the fastener is a helical coil fastener. The applicator has a

15 storage chamber extending from a distal end of the expandable portion, the storage chamber containing at least one helical coil fastener.

Preferably, the third control is connected to the fastener carrying slider by a wire formed of a shape memory material.

Alternately, the fastener driving head is configured to drive a

20 conventional staple into tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments are described herein with reference to the drawings, wherein:

FIG. 1 is a perspective view of a first embodiment of a coil fastener applier for use in installing a prosthetic graft assembly;

5 FIG. 2 is a perspective view of the distal end of the coil fastener applier with an onion assembly in an expanded condition;

FIG. 3 is a perspective view of the distal end of the coil fastener assembly with the onion assembly in the expanded condition and a staple driving head pivoted 90°;

10 FIG. 4 is a view similar to FIG. 3 illustrating a slider extending from the staple driving head and a staple being ejected from the slider;

FIGS. 5-7 are views of the distal end of the coil fastener applier with the onion assembly expanded;

15 FIGS. 8-10 are views of the distal end of coil fastener applier with the staple driving head pivoted 90°;

FIG. 11 is a side view, partially shown in section, of the fastener driving head pivoted 90°;

FIG. 12 is a perspective view illustrating a driving wire;

20 FIG. 13 is a perspective view of a slide associated with the staple driving head;

FIG. 14 is a perspective view of the instrument handle assembly;

FIG. 15 is a top plan view of the instrument handle assembly;

FIG. 16 is a perspective view of the first embodiment prior to use;

FIG. 17 is a perspective view of the first embodiment during testing;

FIG. 18 is a perspective view, partially shown in section, illustrating the distal end of the coil fastener applier positioned within an aneurysm site;

5 FIG. 19 is a perspective view, similar to FIG. 16, with the staple driving head pivoted 90° and a staple being inserted through graft material into a vessel wall;

FIG. 20 is a perspective view of a novel graft assembly positioned about the distal end of a coil fastener applier;

FIGS. 21-22 are perspective views of an alternative staple driving head;

10 FIGS. 23-24 are perspective views of the staple driving head of FIG. 21 without the outer casing;

FIG. 25 is a perspective view of the distal end of a coil fastener applier with a further alternative fastener applying head;

FIG. 26 is a perspective view of the alternative fastener driving head;

15 FIGS. 27-28 are further alternative views of the staple driving head.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIG. 1, there is illustrated a novel coil fastener applier 10 for use in installing graft material. In general, applier 10 generally includes a handle assembly 12 having an elongated flexible shaft 14 extending from a distal end 18 of the handle assembly 12. An onion assembly 16 is provided at the distal end 18 of elongated shaft 14. A coil fastener storage chamber 20 extends from a distal end 22 of the onion assembly 16 and terminates in an end cap 24.

Controls are provided on the handle assembly for various functions. A distal thumb wheel 26 is provided for expanding the onion assembly. A central thumb wheel 28 is provided for pivoting a fastener driving head 90° relative to the elongated shaft and rotating and indexing the fastener driving head between the various wings of the onion assembly. A lock tab 30 secures central thumb wheel 28 in position. An elongated proximal knob 32 is provided for extending a slide portion of the fastener driving head past the expanded onion assembly and for driving a fastener, such as, for example, a helical coil fastener out of the fastener driving head and through graft material and into tissue. A release lever 34 may also be provided on the handle assembly 12 for releasing the extended slide.

Referring to FIGS. 2-4, there is illustrated the distal end 36 of the applicator 10 with the onion assembly 16 in an expanded condition. Onion assembly 16, having wings 40, is expanded in a conventional manner by moving an inner rod or wire connected to distal end 22 of onion assembly 16 relative to shaft 14 which is connected to a proximal end 38 of the onion assembly. A fastener driving head 42 is located within onion assembly 16.

Referring to FIGS. 3-4, there is illustrated fastener driving head 42 pivoted 90° relative to elongated shaft 14.

Specifically, referring to FIG. 4, there is illustrated fastener driving head 42 pivoted 90° relative to elongated shaft 14 and a slider 44 extended out of fastener driving head 42 to provide compression to graft material (FIG. 19). A helical coil fastener 46 is illustrated partially driven out of slider 44. This may be done to test the

operation of applicer 10 but, however, in use, the fastener 46 is not driven out of slider 44 until compression has been applied to the graft material.

Referring to FIGS. 5-7, there is illustrated the distal end 36 of applicator 10 with the onion assembly 16 in an expanded condition. Referring to FIG. 6, there is illustrated the fastener driving head 42 in longitudinal alignment with the elongated shaft 10 and fastener storage chamber 20 which extends distally of the onion assembly 16. Chamber 20 is provided to contain a plurality of helical coil fasteners 46 for use with fastener driving head 42. With fastener driving head 42 in longitudinal alignment with chamber 20, slider 44 can be extended to remove and load a fastener 46 from chamber 20 into fastener head 42. Extending distally from the fastener storage chamber 20 is end cap 24. Preferably, end cap 24 includes a bore 48 therethrough for receipt of a conventional guidewire.

As shown, a proximal end 50 of end cap 24 is threaded to a distal end 52 of storage chamber 20 and a proximal end 54 of storage chamber 20 is threaded to distal end 22 of onion assembly 14. Thus, chamber 20 forms a detachable loading unit for use with applicer 10. A plurality of helical coil fasteners are provided within chamber 20 about a mandrel 56.

Referring to FIGS. 8-10, there is illustrated the distal end 36 of applicer 10 with fastener driving head 42 pivoted 90° relative to elongated shaft 14. As specifically shown in FIG. 10, fastener driving head 42 is pivoted by means of a wire connected to control thumb wheel 28. A flexible, and preferably, shape memory wire 58 such as, for example, a Nitinol or Tinel wire which can be moved to extend and

retract slider 44. Wire 58 can also be rotated within the elongated shaft and head 42 to drive a fastener 46 (positioned on a mandrel) into tissue. A proximal end of wire 58 is connected to proximal knob 32.

Referring to FIG. 11, there is illustrated the distal end 36 of applicator 10 with the fastener driving head 42 pivoted 90° relative to the elongated shaft 14. As illustrated, helical coil fastener 46 is contained within slider 44 and can be driven out of the slider 44 by a mandrel 60. Mandrel 60 includes a longitudinal bore 62 for receipt of an end of the driving wire (not shown). In addition to moving slider 44 by axially moving the wire within elongated shaft 14, helical coil fastener 46 can be rotated out of the fastener driving head 42 by rotation of the driving wire. A guide 64 is preferably provided within the distal end 18 of elongated shaft 14 so as to guide the driving wire around the 90° bend. It should be noted that to load a helical coil fastener 46 from the supply chamber 20 into the fastener driving head 42, the fastener driving head 42 is pivoted to be in longitudinal alignment with the elongated shaft 14 and thus slider 44 can then be extended such that the mandrel 60 contained therein contacts mandrel 56 in the storage chamber 20, and the wire rotated in a reverse direction to draw a helical coil fastener 46 out of the chamber 20 and into slider 44.

FIG. 12 illustrates the driving wire 58 within fastener driving head 42 and slider 44.

FIG. 13 illustrates an enlarged view of slider 44 which includes teeth 66 which are useful in engaging the graft material such that rotation of a coil fastener out of the slider does not rotate or disturb the graft material.

Referring now to FIGS. 14 and 15, there are illustrated views of the handle assembly 12 and associated controls. As noted above, controls are provided for operating the various functions. Distal thumb wheel 26 is provided for expanding the onion assembly. Central thumb wheel 28 is provided for pivoting fastener driving head 42 90° and indexing by 60° the fastener driving head 42 relative to the elongated shaft 14. The head 42 is pivoted 90° by moving central thumb wheel 28 longitudinally and indexed 60° by rotation of wheel 28. Indexing can only occur with head 42 in alignment with the shaft 14. Lock tab 30 adjacent the central wheel 28 locks and releases the fastener driving head 42 in the 90° position.

A ratchet feature 68 is provided with the central knob to control the indexing. Elongated proximal knob 32 is connected to a proximal end of wire 58 and is provided to move slider 44 in the fastener driving head 42 into engagement with graft material and/or tissue by longitudinal movement of knob 32. Rotation of the knob 32 rotates a helical coil fastener contained within the fastener driving head 42 out of the slider 44 and into tissue and is used to load a fastener 46 within the slider 44. A release lever 34 adjacent the proximal knob 32 is provided to maintain the slider in an extended position by releasably engaging an edge 72 of knob 32. Proximal knob 32 includes fine threads 70 for precisely rotating the driving wire 58. A guide block 74 is provided within assembly 12 to guide the various control wires or cables.

Referring now to FIGS. 16 and 17, prior to use, the control unit is actuated so as to draw a helical coil fastener out of the supply and into the slider. As

shown in Sheet 19, operation of the onion assembly, pivoting heads and slider may be tested prior to use. The complete test, and in fact, operation procedure is as follows:

First rotate distal thumb wheel 26 to open and expand onion assembly 16. Next, rotate proximal knob 32 to load fastener 46 into mandrel 60. Then pull
5 central wheel 28 and lock with lock tab 30 into position to pivot head 42 to 90° position. Next, push in (proximal) knob 32 by a desired amount and ratchet in place to extend slider 44. Rotate (proximal) knob 32 to fire fastener out of slider 44. Actuate release lever 34 to retract slider 44. Release lock tab 30 to pivot head 42 to return to in-line position. Rotate proximal knob 32 to reload pivoting head 42 with fastener 46.
10 Rotate central wheel 28 in forward position to index pivoting head 42 and repeat firing sequence.

Referring to FIGS. 18 and 19, in use the distal end 36 of the applier 10, including onion assembly 16 is positioned at the aneurism site by advancing the end cap over a guidewire (not shown).

15 Referring to FIG. 19, once in position, the handle controls are actuated to expand the onion assembly 16 and pivot the fastener drive head 42 90° relative to the elongated shaft 14. Once pivoted 90°, slider 44 is extended out of the head 42 and into compressive engagement with graft material A positioned within the aneurism site. Subsequently, the handle assembly is actuated to rotate the helical coil fastener 46 out
20 of slider 44 through the graft material A and into tissue B to secure the graft material A within the aneurism site.

Referring now to FIG. 20, there is illustrated a novel graft assembly for use with the disclosed applicators. In particular, the graft assembly 80 includes a section of graft material 82 having a generally flat expandable Nitinol ring 84 positioned at one or both ends of the graft material 82. The Nitinol ring 84 is provided to maintain the graft material 82 in expanded engagement with the walls of the tissue section or a vessel during the fastening operation. Nitinol ring 84 may have various other configurations such as round, narrow, etc.

The Nitinol ring 84 may be supported about the onion assembly by additional arms, associated with the onion assembly, which flex to an open condition as the onion assembly is expanded within the graft material. Additionally, there may also be provided longitudinal struts 86 affixed within graft material 82 and terminating in hooks 88. Hooks 88 are configured such that upon expansion of the onion assembly and thus the Nitinol ring 84, hooks 88 are driven into tissue to assist in preventing longitudinal migration of the graft assembly 80 within the aneurism site alone or in addition to affixing the graft assembly 80 with helical coil fasteners or other staple type fasteners. Graft material 82 may be of a suitable known material, such as, for example, Bifurcated Arterial Graft Arterial Graft Surgical Mesh. Struts 86 and hooks 88 may be formed of various suitable biocompatible material such as polymers, and/or stainless steel, or other similar metals.

Referring to FIGS. 21-24, there is illustrated an alternative embodiment of a pivoting and driving head assembly for use with the disclosed fastener applier 90. Head assembly 90 includes a housing 92 which is pivotally mounted on shaft 124.

Instead of utilizing a Nitinol wire to pivot a staple driving head 90° relative to the elongated shaft 14, a pair of beveled gears 94 and 96 and a clutch mechanism 98 are provided to pivot the head and drive a helical coil fastener out of slider 100. Clutch mechanism 98 may be provided to engage and disengage the driving mechanism with fastener driving head 90.

With regard to FIGS. 21-24, head assembly 90 generally includes a housing 92 enclosing a first beveled gear 94 and a second beveled gear 96. A clutch mechanism 98 is provided within housing 92. As shown in FIG. 21, head assembly 90 also includes a slider 100 having slider teeth 101 and a staple driving mandrel 102.

Referring to FIGS. 23 and 24, wherein housing 92 has been removed, head assembly 90 includes a loading connecting nut 104 and a firing connecting nut 106. Connecting nuts 104 and 106 are configured to releasably engage a drive mechanism associated with a fastener applier such that when head assembly 90 is in longitudinal alignment with elongated shaft 14, drive mechanism will engage loading connecting nut 104 to facilitate loading a fastener into head assembly 90 and when head assembly 90 is pivoted 90° the actuating mechanism will engage firing connecting nut 106 to rotate the mandrel 02 and advance the fastener out of head assembly 90. As the fastener is being driven out of head assembly 90 into the graft, the shaft assembly moves forward. At the end of the stroke, the threaded sleeve of the clutch mechanism used to thread in pivot head housing and rotates until changing the direction of rotation. As shown, threaded sleeve 108 surrounds a generally D-shaped shaft 110 and is biased by a spring 112.

Referring now to FIGS. 25-28, there are illustrated various views of an alternative staple driving head 120. In particular, this embodiment of a staple driving head utilizes conventional staples in conjunction with a staple driver and an anvil to secure graft material within a vessel. The head 120 includes links 122 to pivot the head
5 90° relative to an associated shaft. As specifically shown in FIG. 26, the staple driving head 120 includes a body portion 124 having a longitudinally movable staple driving or pusher plate 126, and a feed spring 128 for biasing a staple stack toward an anvil 130. A tension device 132 having a rod 134, a spring 136 around rod 134, and an adjustment screw 138 are provided to return head 120 from a pivoted 90° position to a position
10 longitudinally aligned with a distal end of a modified shaft 140 (FIG. 27). While not specifically illustrated, it is contemplated that a stack or plurality of conventional staples may be provided adjacent the staple biasing plate 126 and anvil 130 to provide a supply of more than one staples within the staple driving head.

Each of the alternative staple driving heads illustrated in FIGS. 21-24
15 and FIGS. 25-28 may be utilized in a manner similar to that discussed with respect to FIGS. 1-19 for securing a graft material within an aneurism site.

WHAT IS CLAIMED IS:

1. An endovascular fastener applicator for endoluminally fastening a prosthetic graft to a vessel with at least one fastener comprising:

a tubular body configured for positioning within a vessel;

5 an expandable portion disposed adjacent a distal end of the tubular body and being expandable to support a prosthetic in contact with an inner surface of a vessel;

a fastener applying head rotatably mounted on the distal end of the tubular body and movable between a load position longitudinally aligned with the tubular and a firing position oriented approximately 90° with respect to the tubular
10 body; and

a handle assembly mounted on a proximal end of the tubular body.

2. The applicator as recited in claim 1, wherein the handle assembly has a first control to expand the expandable portion.

15 3. The applicator as recited in claim 1, wherein the handle assembly includes a second control to pivot the fastener driving head to the firing position.

4. The applicator as recited in claim 3, wherein the second control also rotates the fastener driving head about the longitudinal axis of the tubular body.

5. The applicator as recited in claim 3, wherein the handle assembly
20 includes a third control to move a fastener out of the fastener driving head and into tissue.

6. The applicator as recited in claim 5, wherein the third control further moves a fastener carrying slider into engagement with tissue.

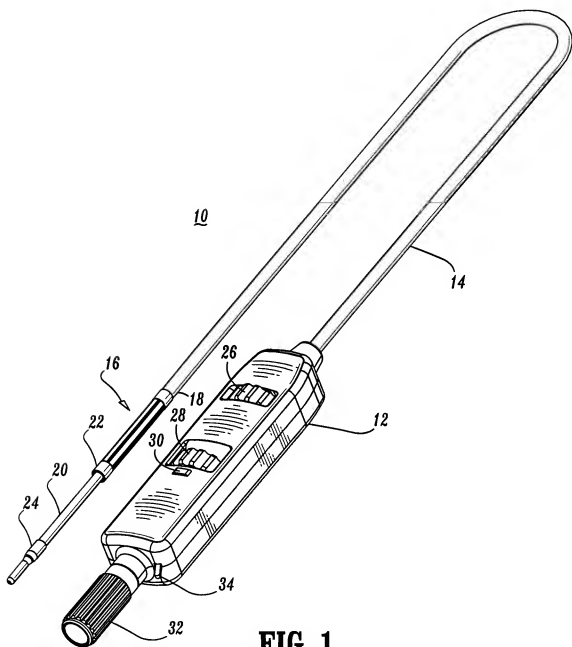
7. The applicator as recited in claim 1, wherein the fastener is a helical coil fastener.

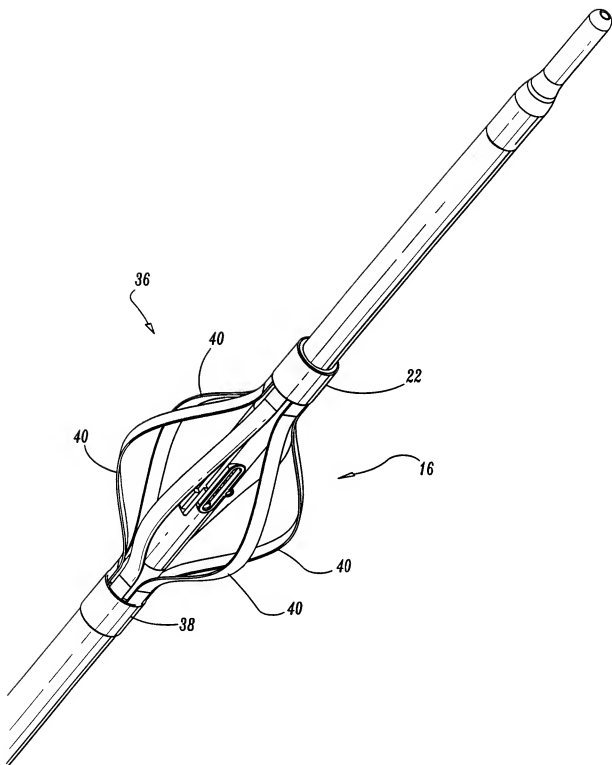
5 8. The applicator has recited in claim 7, further comprising a storage chamber extending from a distal end of the expandable portion, the storage chamber containing at least one helical coil fastener.

9. The applicator as recited in claim 3, wherein the third control is connected to the fastener carrying slider by a wire formed of a shape memory material.

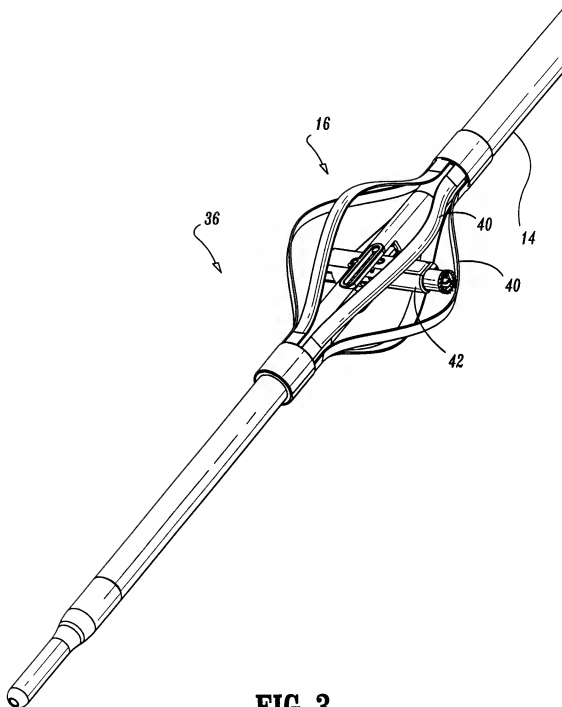
10 10. The applicator as recited in claim 1, wherein the fastener is a conventional staple.

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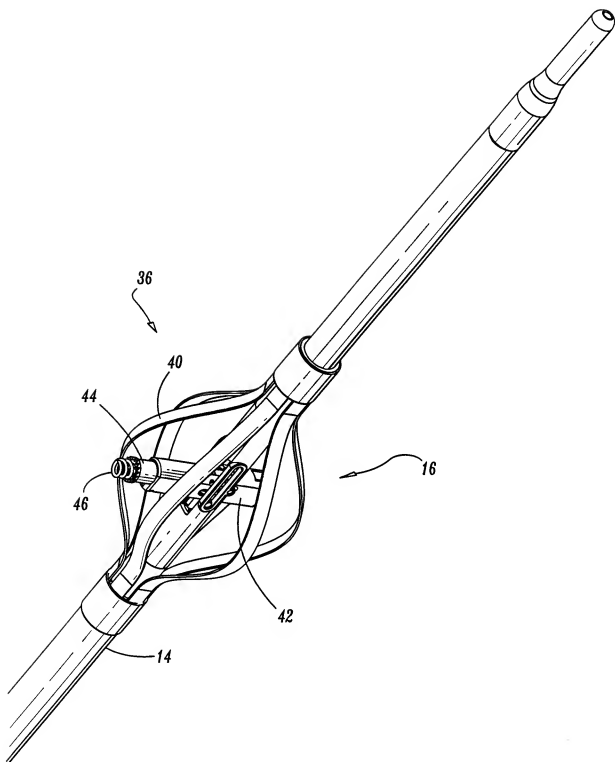
**FIG. 1**

**FIG. 2**

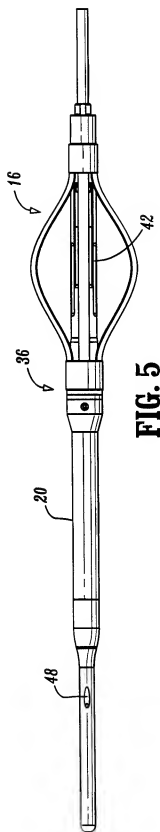
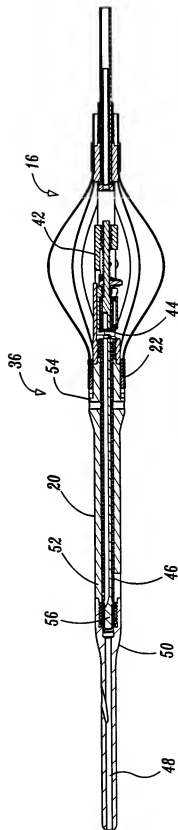
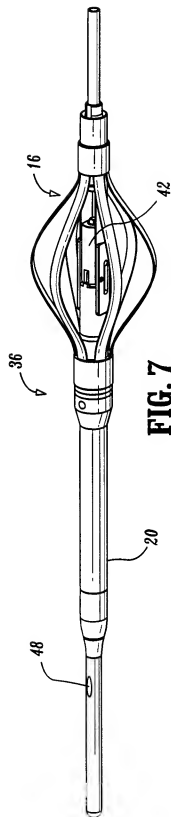
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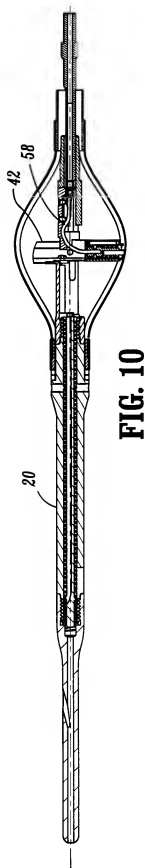
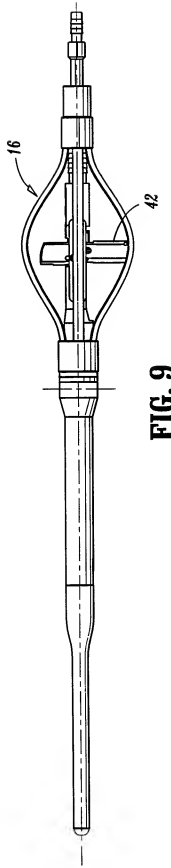
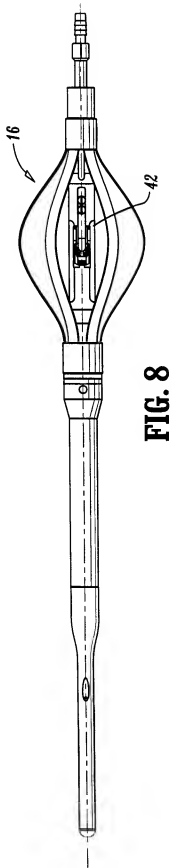
**FIG. 3**

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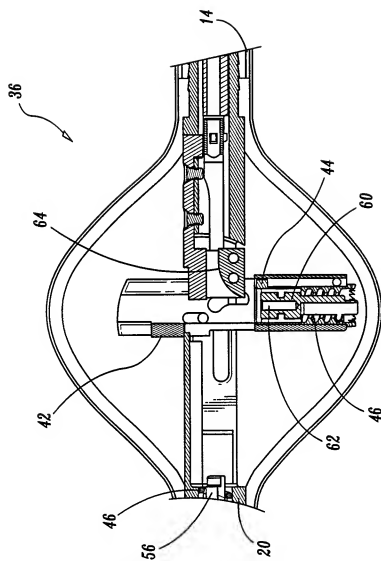
**FIG. 4**

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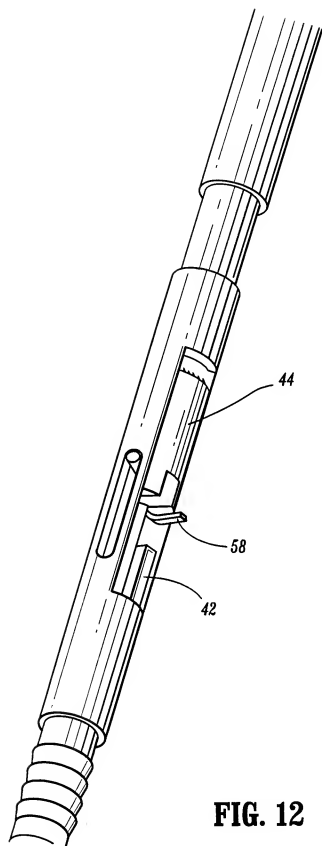
**FIG. 5****FIG. 6****FIG. 7**



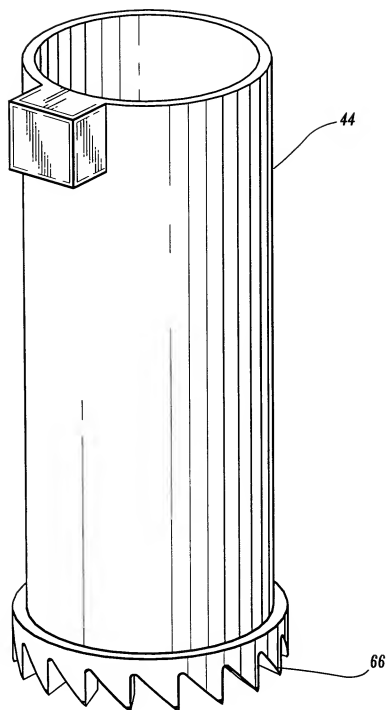
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**FIG. 11**

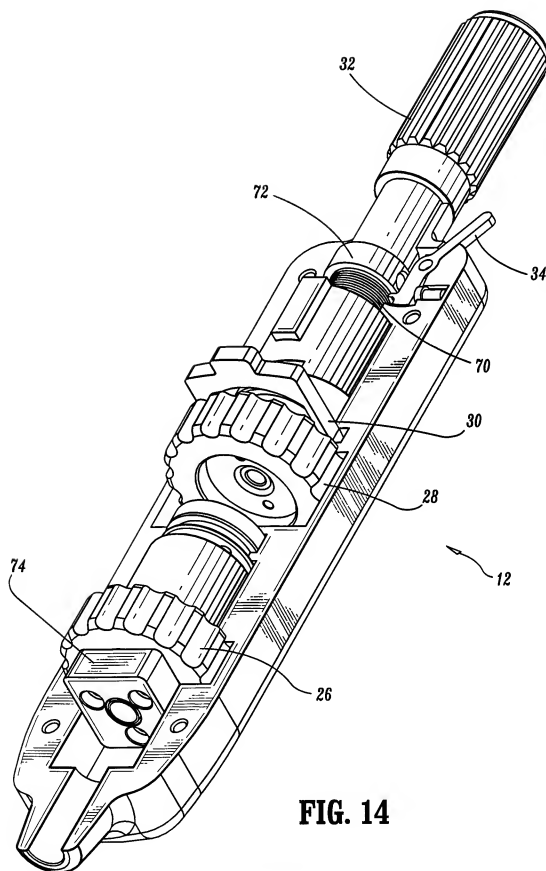
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**FIG. 12**

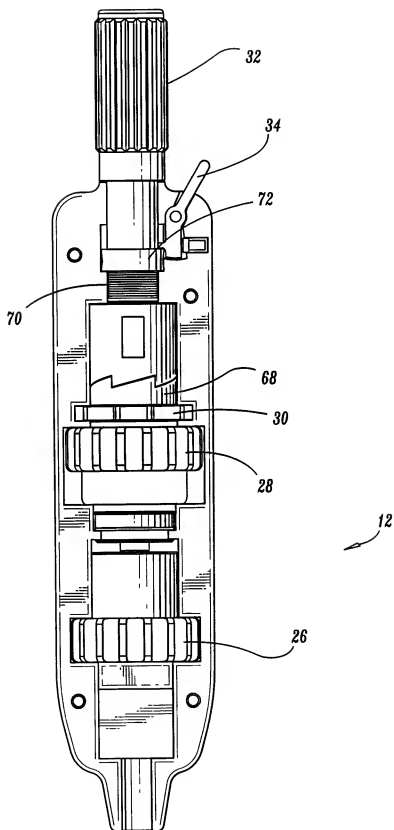
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**FIG. 13**

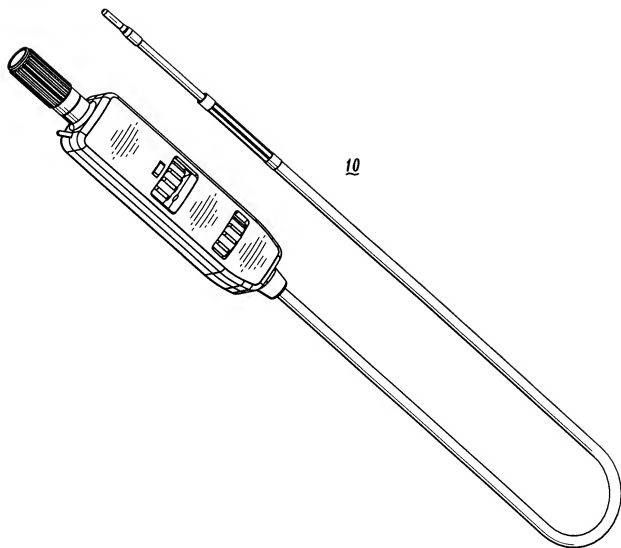
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**FIG. 14**

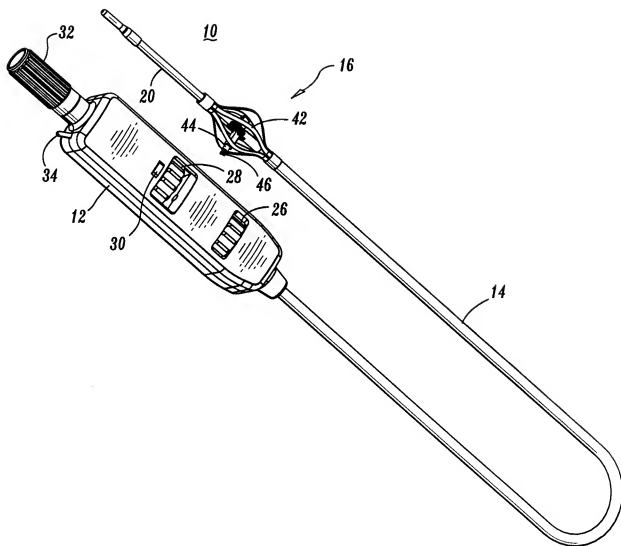
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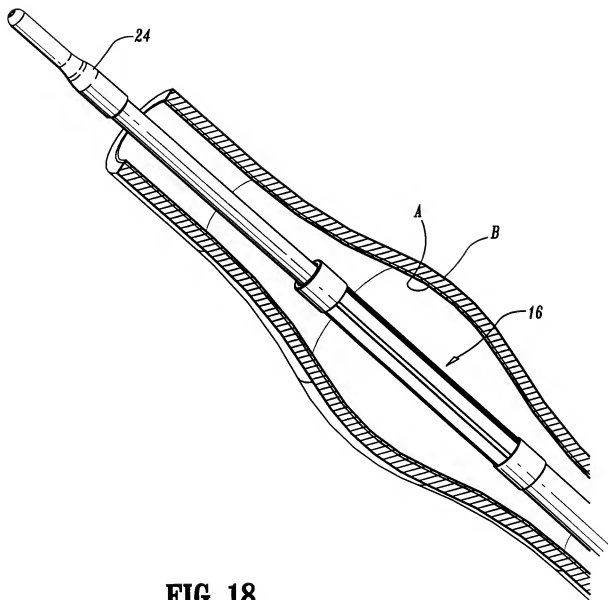
**FIG. 15**

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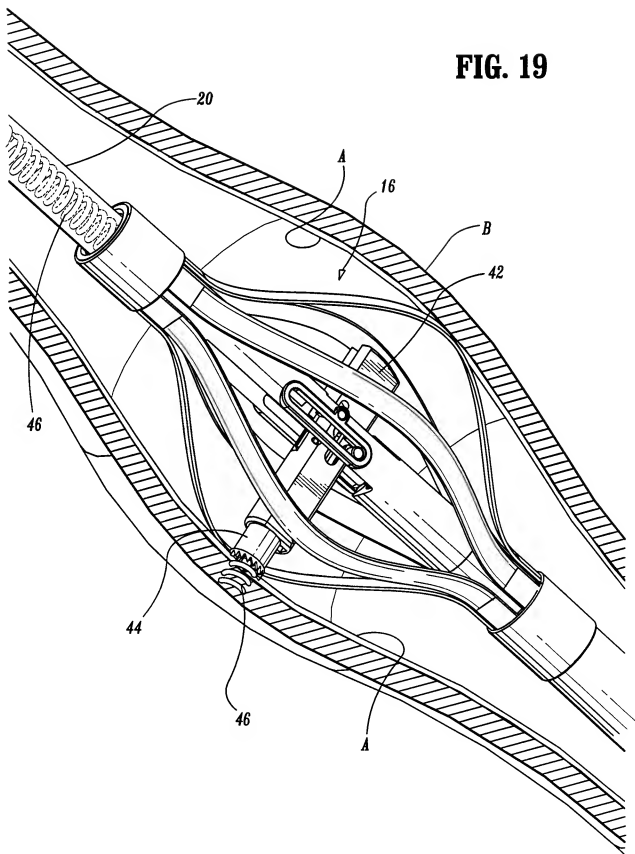
**FIG. 16**

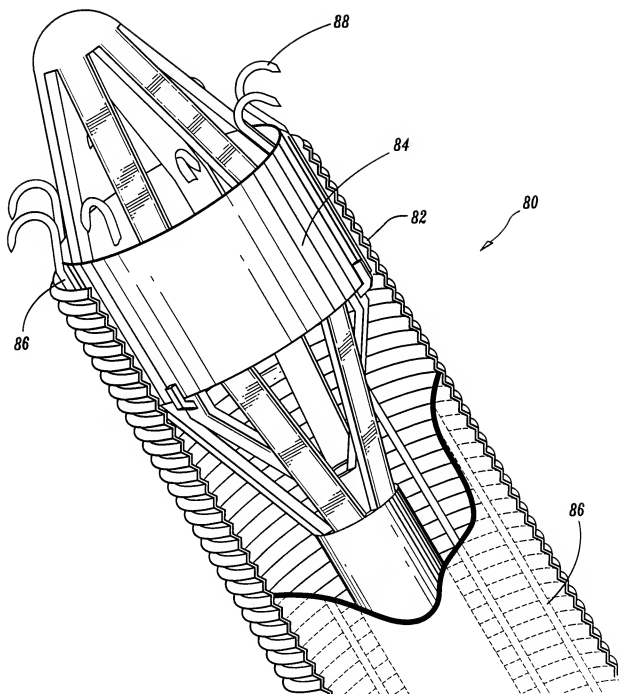
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**FIG. 17**

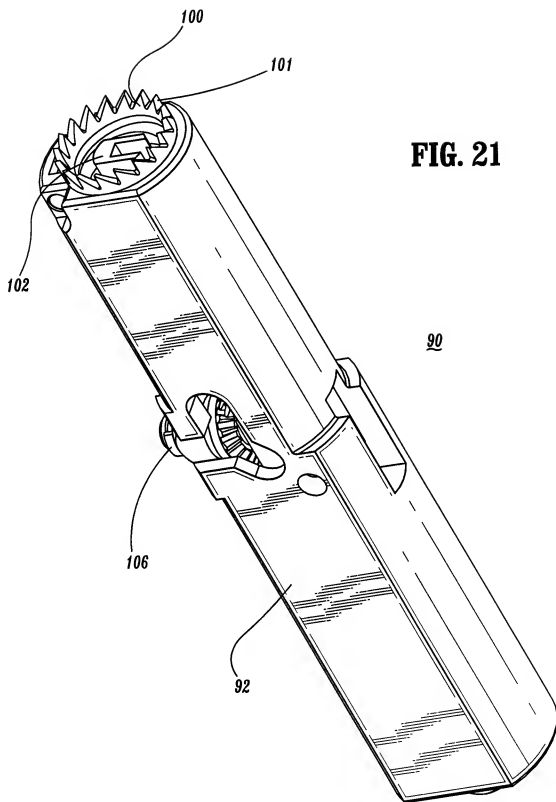
**FIG. 18**

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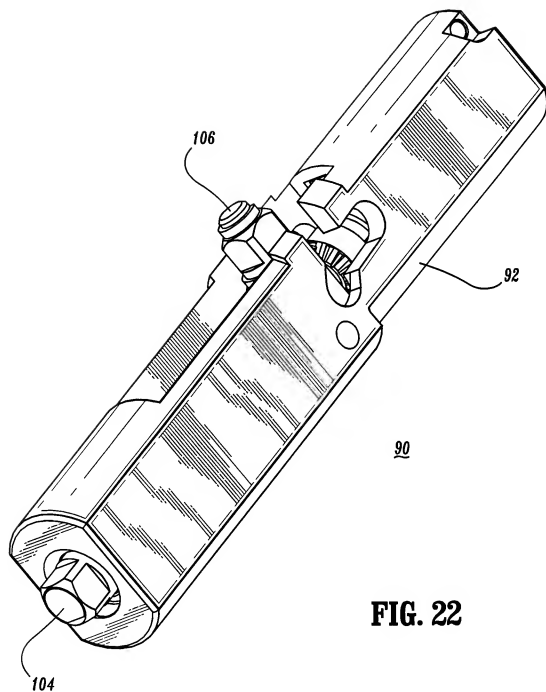
FIG. 19

**FIG. 20**

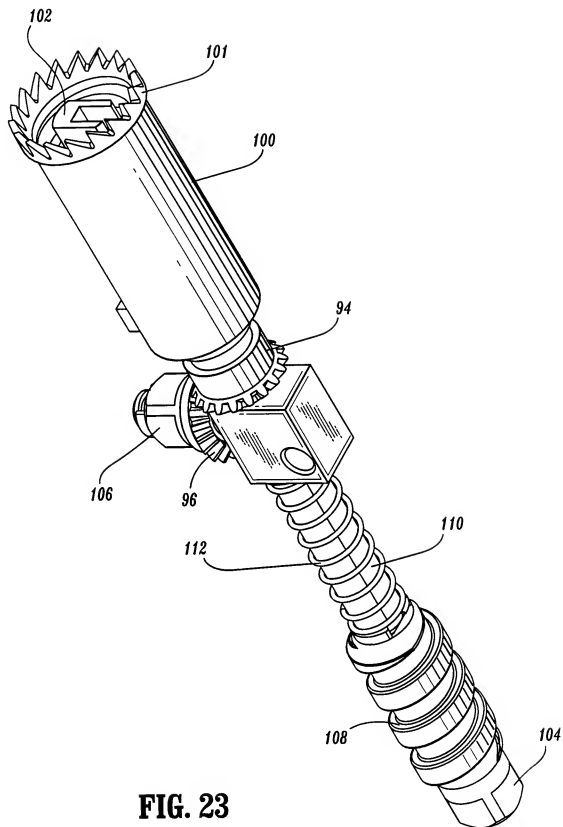
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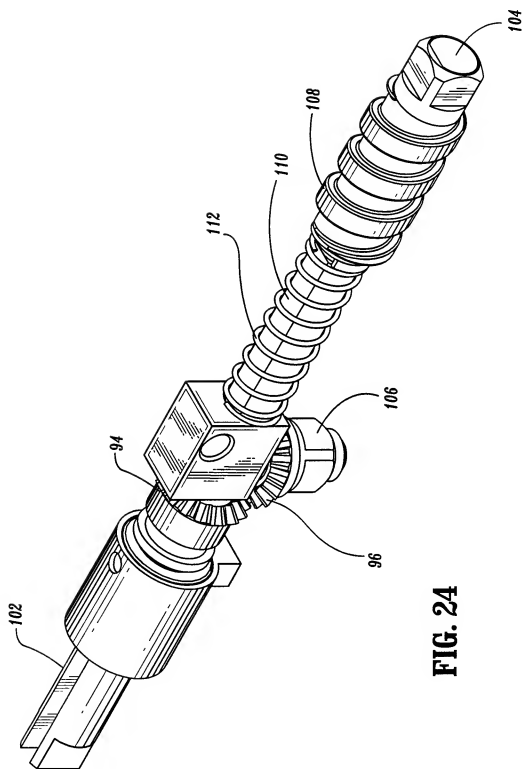
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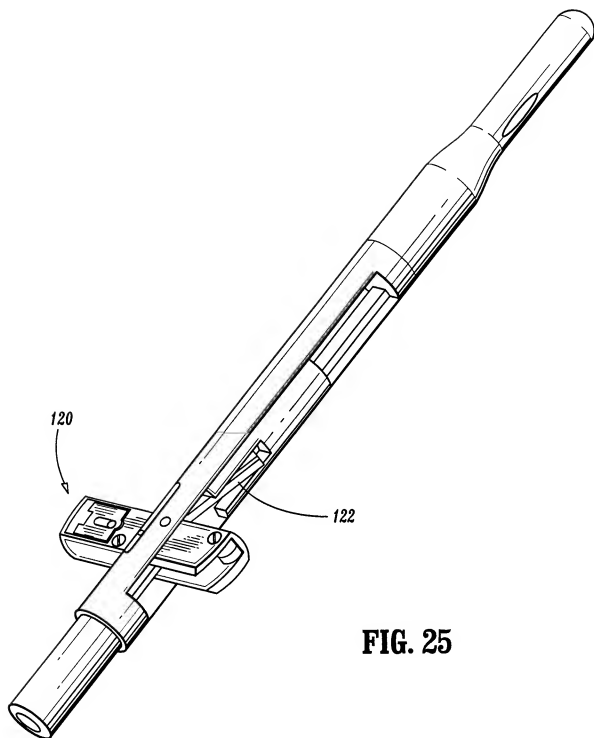
**FIG. 22**

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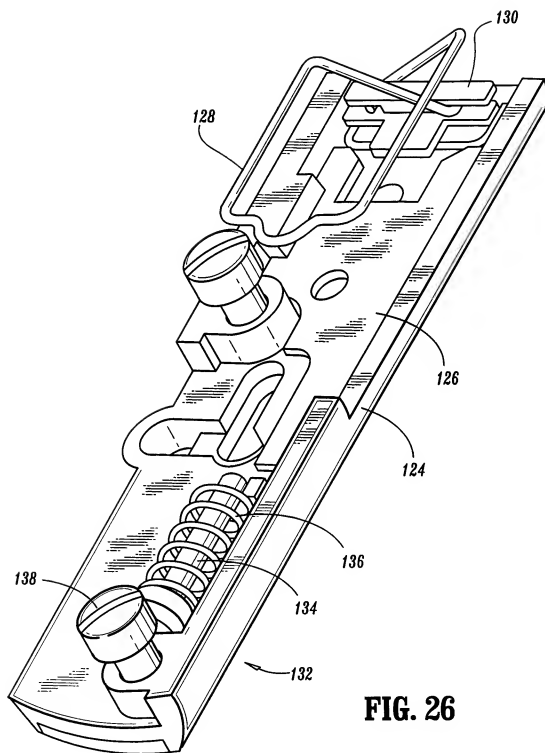
**FIG. 23**

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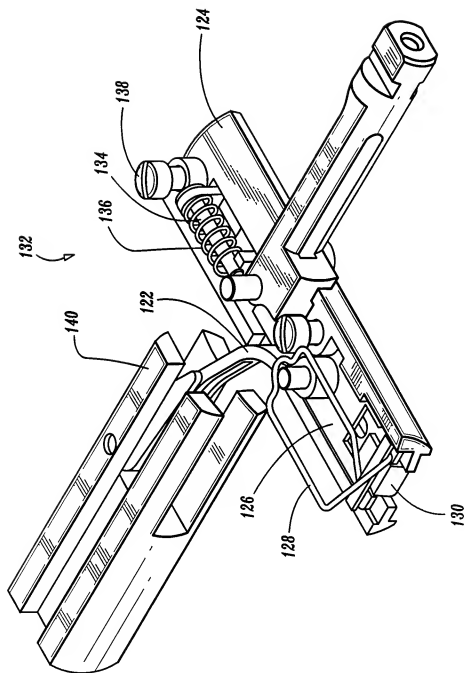
**FIG. 24**

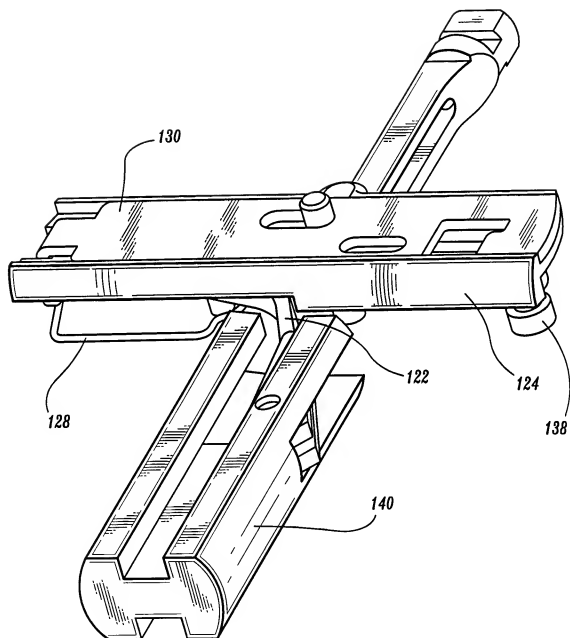
**FIG. 25**

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**FIG. 26**

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**FIG. 27**

**FIG. 28**

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/10921**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) :A61B 17/22, 24; A61M 29/00

US CL :606/113, 114, 159, 194, 198

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/113, 114, 159, 194, 198

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

BRS

Search Terms: catheter, graft, delivery, fenestrat\$, splay\$, slotted, basket, vasc\$ or cardio\$

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,577,631 A (KREAMER) 25 March 1986, entire document.	1-10
X	US 5,609,628 A (KERANEN) 11 March 1997, entire document.	1-10
A	US 5,643,313 A (LEVIN) 01 July 1997, entire document.	1-10

☐ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

* Special categories of cited documents

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"E" earlier document published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

28 JULY 2000

Date of mailing of the international search report

28 AUG 2000

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Washington, D.C. 20231

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